Australian Government

Department of Health, Disability and Ageing

PBS

Schedule of Pharmaceutical Benefits

Highly Specialised Drugs Program

Effective 1 September 2026

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ISSN 1037-3667

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislation website at www.legislation.gov.au.

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Fees, Patient Contributions and Safety Net Thresholds

The following fees, patient contributions and safety net thresholds apply from 1 September 2026 and are included, where applicable, in prices published in the Schedule.

Dispensing Fees:	Ready-prepared	$9.24
	Dangerous drug fee	$5.73
	Extemporaneously-prepared	$11.28
	Allowable additional patient charge*	$2.79
Additional Fees (for safety net prices):	Ready-prepared	$1.54
	Extemporaneously-prepared	$1.99
Patient Co-payments:	General	$25.00
	Concessional	$7.70
Safety Net Thresholds:	General	$1748.20
	Concessional	$277.20
Safety Net Card Issue Fee:		$12.78

* The allowable additional patient charge is a discretionary charge to general patients if a pharmaceutical item has a dispensed price for maximum quantity less than the general patient co-payment. The pharmacist may charge general patients the allowable additional fee but the fee cannot take the cost of the prescription above the general patient co-payment for the medicine. This fee does not count towards the Safety Net threshold.

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits - Highly Specialised Drugs Program are effective from 1 September 2026. The Schedule is updated on the first day of each month and is also available at www.pbs.gov.au.

Highly Specialised Drugs Program (Private Hospital)

Additions

Addition – Item

15508F **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

15515N **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

15509G **OBINUTUZUMAB**, obinutuzumab 1 g/40 mL injection, 40 mL vial *(Gazyva)*

15516P **OBINUTUZUMAB**, obinutuzumab 1 g/40 mL injection, 40 mL vial *(Gazyva)*

Deletions

Deletion – Note

14679N **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
13244C	**RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*	M	M,N
13231J	**RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*	M	M,N

Alteration – Note

9674E **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11432Q **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remsima, Renflexis)*

10880P **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10884W **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10887B **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

13804M **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara, Steqeyma, Wezlana)*

Alteration – Restriction

14189T **ANIFROLUMAB**, anifrolumab 300 mg/2 mL injection, 2 mL vial *(Saphnelo)*

6100C **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Dr.Reddy's, Azacitidine Juno, Azacitidine MSN, Azacitidine SXP)*

11996J **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11997K **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12313C **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12316F **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

14962L **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices *(Dupixent)*

14999K **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12294C **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12310X **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

14960J **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

14965P **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices *(Dupixent)*

9674E **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11432Q **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remsima, Renflexis)*

2798G **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

9642L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11036W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11966T **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12058P **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12071H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

2796E **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

9643M **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11063G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11969Y **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12004T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12060R **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

9644N **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11042E **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11965R **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12020P **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12069F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

14610Y **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

14615F **LENALIDOMIDE**, lenalidomide 20 mg capsule, 14 *(Lenalide)*

14624Q **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

14631C **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

9645P **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11055W **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12018M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12068E **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12051G **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12052H **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

13242Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11531X **MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*

10110D **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

10956P **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

11840E **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

14904K **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device *(Xolair)*

14919F **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo)*

14921H **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device *(Xolair)*

10122R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

10968G **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

11864K **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

14923K **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL pen device *(Xolair)*

14927P **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

14928Q **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL pen device *(Xolair)*

14951X **OMALIZUMAB**, omalizumab 300 mg/2 mL injection, 2 mL pen device *(Xolair)*

14953B **OMALIZUMAB**, omalizumab 300 mg/2 mL injection, 2 mL pen device *(Xolair)*

10880P **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10884W **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10887B **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

11167R **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11172B **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11166Q **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

11174D **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

13244C **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13231J **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

15363N **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device *(Tezspire)*

15364P **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device *(Tezspire)*

13804M **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara, Steqeyma, Wezlana)*

14679N **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Alteration – Manufacturer Code

		From	*To*
11164N	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN
13255P	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN
13804M	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN

Supply Only

Supply Only – Period Commencing

11412P **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Advance Notices

1 October 2026

Deletion – Brand

9615C *Nepexto, GQ* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

13332Q *Nepexto, GQ* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

2798G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

9642L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11036W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11966T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12038N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12058P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12071H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12984J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

13642B *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

15103X *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

15418L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2796E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9643M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11063G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11969Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12004T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12050F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12060R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12980E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

13658W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

15079P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

15485B *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

9644N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11042E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11965R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12011E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12020P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12069F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12986L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

13657T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

15073H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

15488E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

9645P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11055W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12018M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12037M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12068E *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12993W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

13660Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

15096M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

1 December 2026
Deletion – Brand

11838C *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

Highly Specialised Drugs Program (Public Hospital)

Additions

Addition – Item

15511J **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

15525D **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

15510H **OBINUTUZUMAB**, obinutuzumab 1 g/40 mL injection, 40 mL vial *(Gazyva)*

15526E **OBINUTUZUMAB**, obinutuzumab 1 g/40 mL injection, 40 mL vial *(Gazyva)*

Deletions

Deletion – Note

14670D **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Alterations

Alteration – Authorised Prescriber

		From	*To*
13238R	**RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*	M	M,N
13245D	**RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*	M	M,N

Alteration – Note

9654D **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11423F **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remsima, Renflexis)*

10886Y **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10883T **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10882R **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

13781H **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara, Steqeyma, Wezlana)*

Alteration – Restriction

14195D **ANIFROLUMAB**, anifrolumab 300 mg/2 mL injection, 2 mL vial *(Saphnelo)*

9597D **AZACITIDINE**, azacitidine 100 mg injection, 1 vial *(Azacitidine Accord, Azacitidine Dr.Reddy's, Azacitidine Juno, Azacitidine MSN, Azacitidine SXP)*

11994G **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

11995H **BENRALIZUMAB**, benralizumab 30 mg/mL injection, 1 mL pen device *(Fasenra Pen)*

12309W **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12318H **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

14959H **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices *(Dupixent)*

15041P **DUPILUMAB**, dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes *(Dupixent)*

12293B **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

12302L **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

14964N **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices *(Dupixent)*

15032E **DUPILUMAB**, dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes *(Dupixent)*

9654D **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

11423F **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remsima, Renflexis)*

2799H **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

5783J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11029L **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11967W **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12034J **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12035K **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

2802L **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

5784K **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11064H **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11968X **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12061T **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12070G **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

5785L **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11062F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11964Q **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12012F **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12026Y **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

14588T **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

14592B **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

14623P **LENALIDOMIDE**, lenalidomide 20 mg capsule, 14 *(Lenalide)*

14632D **LENALIDOMIDE**, lenalidomide 20 mg capsule, 21 *(Lenalide, Lenalidomide Sandoz)*

5786M **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

11041D **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12019N **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12059Q **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21 *(Lenalide, Lenalidomide Dr.Reddy's, Lenalidomide Sandoz, Revlimid)*

12007Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

12064Y **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

13237Q **MEPOLIZUMAB**, mepolizumab 100 mg/mL injection, 1 mL pen device *(Nucala)*

11552B **MIDOSTAURIN**, midostaurin 25 mg capsule, 112 *(Rydapt)*

10118M **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

10967F **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

11835X **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo, Xolair)*

14947Q **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe *(Omlyclo)*

14949T **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device *(Xolair)*

14950W **OMALIZUMAB**, omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device *(Xolair)*

10109C **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

10973M **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

11824H **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

14884J **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL pen device *(Xolair)*

14922J **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL pen device *(Xolair)*

14948R **OMALIZUMAB**, omalizumab 150 mg/mL injection, 1 mL syringe *(Omlyclo)*

14885K **OMALIZUMAB**, omalizumab 300 mg/2 mL injection, 2 mL pen device *(Xolair)*

14906M **OMALIZUMAB**, omalizumab 300 mg/2 mL injection, 2 mL pen device *(Xolair)*

10886Y **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10883T **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

10882R **PASIREOTIDE EMBONATE**, pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack *(Signifor LAR)*

11179J **PEGVISOMANT**, pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11173C **PEGVISOMANT**, pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

11177G **PEGVISOMANT**, pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack *(Somavert)*

11181L **PEGVISOMANT**, pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack *(Somavert)*

13238R **RUXOLITINIB**, ruxolitinib 5 mg tablet, 56 *(Jakavi)*

13245D **RUXOLITINIB**, ruxolitinib 10 mg tablet, 56 *(Jakavi)*

15403Q **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device *(Tezspire)*

15413F **TEZEPELUMAB**, Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device *(Tezspire)*

13781H **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial *(Stelara, Steqeyma, Wezlana)*

14670D **VEDOLIZUMAB**, vedolizumab 300 mg injection, 1 vial *(Entyvio)*

Alteration – Manufacturer Code

		From	*To*
11182M	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN
13272M	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN
13781H	*Wezlana* – **USTEKINUMAB**, ustekinumab 130 mg/26 mL injection, 26 mL vial	AN	TN

Supply Only

Supply Only – Period Commencing

11424G **INFLIXIMAB**, infliximab 100 mg injection, 1 vial *(Inflectra, Ixifi, Remicade, Remsima, Renflexis)*

Advance Notices

1 October 2026

Deletion – Brand

5733R *Nepexto, GQ* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

13308K *Nepexto, GQ* – **ETANERCEPT**, etanercept 50 mg/mL injection, 4 x 1 mL syringes

2799H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

5783J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11029L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

11967W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 28

12034J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12035K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 14

12039P *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

12985K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

13636Q *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

15106C *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

15487D *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 5 mg capsule, 21

2802L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

5784K *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11064H *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

11968X *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 28

12057N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12061T *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

12070G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 14

12988N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

13661B *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

15067B *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

15451F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 10 mg capsule, 21

5785L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11062F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

11964Q *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 28

12012F *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 14

12026Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12062W *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

12991R *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

13641Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

15078N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

15452G *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 15 mg capsule, 21

5786M *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

11041D *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12019N *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 14

12036L *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12059Q *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

12979D *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

13630J *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

15104Y *Lenalidomide Dr.Reddy's, RI* – **LENALIDOMIDE**, lenalidomide 25 mg capsule, 21

1 December 2026

Deletion – Brand

11855Y *Sevelamer Lupin, GQ* – **SEVELAMER**, sevelamer carbonate 800 mg tablet, 180

Highly Specialised Drugs Program (Community Access)

Deletions

Deletion – Brand

10311Q *Lamivudine Alphapharm, AF* – **LAMIVUDINE**, lamivudine 300 mg tablet, 30

About the Schedule

The Schedule of Pharmaceutical Benefits lists all ready-prepared items subsidised under the Pharmaceutical Benefits Scheme (PBS).

The Schedule is published and is effective on the first day of each month.

For detailed information about the prescribing and supply of pharmaceutical benefits go to www.pbs.gov.au

For information about the operational aspects of the PBS, such as, PBS claiming, authority applications and stationery supplies contact Services Australia at www.servicesaustralia.gov.au

Symbols and Abbreviations Used in the Schedule

*	An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity
‡	A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed
#	A gauge in the dispensed price column indicates that the product is not preconstituted and that the dispensed price therefore included a dispensing fee and where appropriate, an amount for purified water
a or b	Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect
B	Located immediately before an amount in the premium column indicates a brand premium which applies to that particular brand of the item
T	Located immediately before an amount in the premium column indicates a therapeutic group premium which applies to that particular item
S	Located immediately before an amount in the premium column indicates a special patient contribution which applies to that particular item
DPMQ $	Dispensed price for maximum quantity
MRVSN $	Maximum recordable value for safety net
NP	Indicates that the item can be prescribed by an authorised nurse practitioner
MW	Indicates that the item can be prescribed by an authorised midwife
OP	Indicates that the item can be prescribed by an authorised optometrist
DP	Indicates that the item can be prescribed by an authorised dental practitioner

Restricted Benefits

All restricted items have separate headings for authority and non-authority items. In each case these items may be prescribed as pharmaceutical benefits only for use for one of the specified indications. Where more than one indication is specified for an Authority required or Restricted pharmaceutical benefit, each indication is separated from the preceding indication by a semi-colon and commences on the next line. In the case of Authority required (STREAMLINED) items, each restriction will also include a streamlined authority code. The drug may be prescribed as a pharmaceutical benefit for a patient who qualifies under any of the specified indications.

Restricted benefits – above an item indicates where an item can only be prescribed for specific therapeutic uses.

Authority required benefits – above an item indicates that a prescriber must seek approval from Services Australia or the Department of Veterans' Affairs. The prescriber must declare the specific conditions and circumstances that justify the use of these medicines. This is usually done by phone or in writing.

Authority required (STREAMLINED) – authority can be sought electronically.

General Statements

General Statement for Drugs for the Treatment of Hepatitis C

Use the following criteria to determine patient eligibility for subsidisation under the PBS for hepatitis C treating agents.

By writing a PBS prescription, the prescriber is certifying the patient satisfies the qualifying criteria set out below and the use in accordance with the registered indications which differ between agents in this class – refer to the current Product Information for details.

Treatment criteria:

Must be treated by a medical practitioner or an authorised nurse practitioner experienced in the treatment of chronic hepatitis C infection; or in consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in the treatment of chronic hepatitis C infection.

The following information must be provided at the time of application:

- the patient's cirrhotic status (non-cirrhotic or cirrhotic)
- details of the previous treatment regimen (only for requests for sofosbuvir + velpatasvir + voxilaprevir (Vosevi®) or glecaprevir + pibrentasvir (Maviret®) for 16 weeks' treatment in patients who have previously failed a treatment with a regimen containing an NS5A inhibitor).

The following information must be documented in the patient's medical records:

a) evidence of chronic hepatitis C infection:

- antibody to hepatitis C virus (anti-HCV) positive; and
- repeated hepatitis C virus ribonucleic acid (HCV RNA) positive; and

b) evidence of the hepatitis C virus genotype (where possible)

The following matrices identify the regimens which are available for PBS prescription for eligible patients, based on the hepatitis C virus genotype and treatment history.

HEPATITIS C - NON-CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
All genotypes (Pan-genotypic regimens)	**SOFOSBUVIR** + **VELPATASVIR** [12 weeks] OR **GLECAPREVIR** + **PIBRENTASVIR** [8 weeks]	**SOFOSBUVIR** + **VELPATASVIR** [12 weeks] OR **SOFOSBUVIR** + **VELPATASVIR** + **VOXILAPREVIR** [12 weeks] [1] OR **GLECAPREVIR** + **PIBRENTASVIR** [8 or 12 or 16 weeks] [2]

HEPATITIS C – CIRRHOTIC PATIENTS

	TREATMENT NAÏVE	TREATMENT EXPERIENCED
All genotypes (Pan-genotypic regimens)	**SOFOSBUVIR** + **VELPATASVIR** [12 weeks] [3, 4] OR **GLECAPREVIR + PIBRENTASVIR** [12 weeks] [5]	**SOFOSBUVIR** + **VELPATASVIR** [12 weeks] [3, 4] OR **SOFOSBUVIR** + **VELPATASVIR** + **VOXILAPREVIR** [12 weeks] [1] OR **GLECAPREVIR + PIBRENTASVIR** [12 or 16 weeks] [6]

1. SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR [12 weeks] only for patients who have failed an NS5A inhibitor.
2. GLECAPREVIR + PIBRENTASVIR [8 or 12 or 16 weeks] for non-cirrhotic patients:
   - treatment for 8 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;

- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

[3.] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with decompensated cirrhosis. Use in combination with ribavirin.
[4.] SOFOSBUVIR + VELPATASVIR [12 weeks] for patients with genotype 3 infection with compensated cirrhosis. Consider addition of ribavirin.
[5.] GLECAPREVIR + PIBRENTASVIR – A treatment duration of 12 weeks may be considered for patients with compensated cirrhosis, at the discretion of the prescriber.
[6.] GLECAPREVIR + PIBRENTASVIR [12 or 16 weeks] for cirrhotic patients:

- treatment for 12 weeks for treatment-experienced patients with genotypes 1, 2, 4, 5 or 6 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 16 weeks for treatment-experienced patients with genotype 3 who have failed regimens containing peginterferon, ribavirin, and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor;
- treatment for 12 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS3/4A PI;
- treatment for 16 weeks for treatment-experienced patients with genotype 1 who have failed regimens containing an NS5A inhibitor.

Highly Specialised Drugs Program (Private Hospital)

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ALIMENTARY TRACT AND METABOLISM

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Enzymes

PEGUNIGALSIDASE ALFA

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19015

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18930

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18929

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19045

Fabry disease

Treatment Phase: Switching from PBS-subsidised migalastat

Clinical criteria:

- Patient must have received prior treatment with PBS-subsidised migalastat for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial

15483X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,891.64	ELFABRIO [EU]

Various alimentary tract and metabolism products

NITISINONE

Note No increase in the maximum number of repeats may be authorised.

Authority Required

19053

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19057

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**

- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18958

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nitisinone 2 mg capsule, 60

15481T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,218.15	Orfadin [FK]

nitisinone 5 mg capsule, 60

15425W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	2,321.25	Orfadin [FK]

nitisinone 10 mg capsule, 60

15467C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,995.62	Orfadin [FK]

nitisinone 20 mg capsule, 60

15459P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	7,415.80	Orfadin [FK]

NITISINONE

Note No increase in the maximum number of repeats may be authorised.

Authority Required

19055

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19058

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**

- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18959

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nitisinone 4 mg/mL oral liquid, 90 mL

15502X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	4,198.82	Orfadin [FK]

TEDUGLUTIDE

Note Special Pricing Arrangements apply.

Authority Required

11999

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment, **AND**
- The treatment must provide no more than the balance of up to 12 months of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11812Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	19,759.84	Revestive [TK]

TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18198

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; **OR**
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline; **OR**
- The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above.

Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

From 1 September 2021

Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:

(i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and

(ii) the current value (observed over a 4 week timeframe)

Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.

Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11806J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	19,759.84	Revestive [TK]

TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note

A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18986

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to commencing this drug, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:

(i) for a patient of any age, the mean number of days of parenteral support per week,

(ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to commencing this drug. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11795T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	11	0.00	19,759.84	Revestive [TK]

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

AVATROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18297

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15375

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14054

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15340

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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avatrombopag 20 mg tablet, 30

13317X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,650.30	Doptelet [ZO]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18209

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**

- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; **OR**
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

eltrombopag 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14115X	3	3	0.00	*3,733.59	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

15173

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 25 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14119D	3	5	0.00	*3,733.59	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18209

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**

- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; **OR**
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

eltrombopag 50 mg tablet, 28

14107L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	3	0.00	*7,417.95	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16455

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 25 mg tablet, 28

14136B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	0.00	*3,733.59	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

15173

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14143J	3	5	0.00	*7,417.95	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16455

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14127M	3	5	0.00	*7,417.95	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18210

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14129

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13327

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14127

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 25 mg tablet, 28

5827Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,277.36	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18210

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14129

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13327

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14127

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

5828R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,505.48	Revolade [NV]

ROMIPLOSTIM

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18405

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14099

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13396

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14149

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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romiplostim 250 microgram injection, 1 vial

9697J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	523.12	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

9699L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,037.01	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority Required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**

- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6320P NP	2	5	0.00	*242.58	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6321Q NP	2	5	0.00	*448.68	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6488L NP	8	5	0.00	*448.68	Aranesp SureClick [AN]

darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6322R NP	2	5	0.00	*610.44	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6323T NP	2	5	0.00	*738.96	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6489M NP	8	5	0.00	*738.92	Aranesp SureClick [AN]

darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6324W NP	2	5	0.00	*911.42	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6325X NP	2	5	0.00	*1,067.88	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6490N NP	8	5	0.00	*1,067.88	Aranesp SureClick [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6438W NP	2	5	0.00	*1,390.06	Aranesp [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6491P NP	8	5	0.00	*1,390.12	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6326Y NP	2	5	0.00	*1,700.40	Aranesp [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6492Q NP	8	5	0.00	*1,700.36	Aranesp SureClick [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6365B NP	2	5	0.00	*2,509.42	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6493R NP	8	5	0.00	*2,509.40	Aranesp SureClick [AN]

EPOETIN ALFA

Authority Required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**

- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6205N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*446.24	Eprex 3000 [JC]

epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

6206P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*565.78	Eprex 4000 [JC]

epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

6204M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*347.90	Eprex 2000 [JC]

epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

6251B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*192.26	Eprex 1000 [JC]

epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

6302Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*702.10	Eprex 5000 [JC]

epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

6434P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*2,491.46	Eprex 20,000 [JC]

epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

6303R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*831.72	Eprex 6000 [JC]

epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

6305W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,074.96	Eprex 8000 [JC]

epoetin alfa 40 000 units/mL injection, 1 mL syringe

6339P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*830.96	Eprex 40,000 [JC]

epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

6207Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,290.68	Eprex 10000 [JC]

EPOETIN LAMBDA

Authority Required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

9687W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*424.40	Novicrit [SZ]

epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

9688X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*537.96	Novicrit [SZ]

epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

9588P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*667.48	Novicrit [SZ]

epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

9685R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*183.12	Novicrit [SZ]

epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

9590R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*790.62	Novicrit [SZ]

epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9593X NP	2	5	0.00	*1,022.66	Novicrit [SZ]

epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9595B NP	2	5	0.00	*1,228.66	Novicrit [SZ]

epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9686T NP	2	5	0.00	*330.96	Novicrit [SZ]

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority Required (STREAMLINED)

9688

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9574X NP	2	5	0.00	*239.08	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9575Y NP	2	5	0.00	*392.32	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9576B NP	2	5	0.00	*567.06	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9577C NP	2	5	0.00	*730.66	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9578D NP	2	5	0.00	*844.48	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9579E NP	2	5	0.00	*1,201.14	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9580F NP	2	5	0.00	*2,040.54	Mircera [RO]

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18836

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority Required

18741

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13575

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ambrisentan 5 mg tablet, 30

9648T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1,268.99	[a] Ambrisentan Viatris [AL]	[a] PULMORIS [XT]
					[a] Volibris [ZE]	

ambrisentan 10 mg tablet, 30

9649W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1,268.99	[a] Ambrisentan Viatris [AL]	[a] Cipla Ambrisentan [ZU]
					[a] PULMORIS [XT]	[a] Volibris [ZE]

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

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ambrisentan 5 mg tablet, 30

12201E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	1,268.99	[a] Ambrisentan Viatris [AL]	[a] PULMORIS [XT]
				[a] Volibris [ZE]	

ambrisentan 10 mg tablet, 30

12180C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1,268.99	[a] Ambrisentan Viatris [AL]	[a] Cipla Ambrisentan [ZU]
					[a] PULMORIS [XT]	[a] Volibris [ZE]

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bosentan 62.5 mg tablet, 60

12139X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
					[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12425

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

- Patient must be receiving PBS-subsidised treatment with this PAH agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

bosentan 62.5 mg tablet, 60

12143D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18738

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18833

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13571

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bosentan 62.5 mg tablet, 60

6429J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

bosentan 125 mg tablet, 60

6430K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan GH [GQ]	[a] Bosentan RBX [RA]
				[a] Bosentan Viatris [AL]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will

be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 62.5 mg tablet, 60

12148J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH

- BMPR2 mutation
- ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
- Other mutations

- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 125 mg tablet, 60

12146G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	131.47	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan GH [GQ]	[a] Bosentan RBX [RA]
				[a] Bosentan Viatris [AL]	

EPOPROSTENOL

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18208

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13491

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13577

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18401

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18859

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH is established through a prior PBS authority application

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO functional class II status with at least one of the following: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18802

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing the prostanoid agent in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13506

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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epoprostenol 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	0.00	*1,047.54	Veletri [JC]

epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	30	5	0.00	*1,829.04	Veletri [JC]

ILOPROST

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18403

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13491

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13577

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18294

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18859

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH is established through a prior PBS authority application

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO functional class II status with at least one of the following: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18802

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing the prostanoid agent in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13506

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

6456T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	372.81	Ventavis [BN]

MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18836

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18741

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13575

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

macitentan 10 mg tablet, 30

10134J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,348.49	Opsumit [JC]

MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

macitentan 10 mg tablet, 30

12135Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,348.49	Opsumit [JC]

MACITENTAN + TADALAFIL

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

16457

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must be dual combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil; **OR**
- The treatment must be part of triple combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (dual or triple therapy, excluding selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application.

This treatment is not PBS-subsidised for the use as initial therapy

For the purposes of PBS subsidy, a prostanoid is one of: (a) epoprostenol, (b) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination' therapy.

Note If this authority application is to continue combination therapy, but with a change in prostanoid, the 'Initial 3 - change' treatment phase restriction of the new drug outlines the continuing eligibility criteria of that new drug.

Authority Required

16433

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (triple therapy with selexipag)

Clinical criteria:

- The treatment must be part of triple combination therapy consisting of: (i) macitentan, (ii) tadalafil, (iii) selexipag.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (triple therapy with selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application.

This treatment is not PBS-subsidised for the use as initial therapy

The authority application for selexipag must be approved prior to the authority application for this agent.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Macitentan 10 mg + tadalafil 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14828K	1	5	0.00	2,601.32	Opsynvi [JC]

RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority Required

18200

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; **OR**
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm^{-5} measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn*sec*cm^{-5} measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the results from the 3 tests below, to establish baseline measurements, where available:

(i) RHC composite assessment, and

(ii) ECHO composite assessment, and

(iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15271

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15272

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

riociguat 500 microgram tablet, 42

11009K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 1 mg tablet, 42

10990K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 1.5 mg tablet, 42

10974N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 2 mg tablet, 42

11012N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 2.5 mg tablet, 42

10985E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note Special Pricing Arrangements apply.

Authority Required

18215

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13514

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13502

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

riociguat 500 microgram tablet, 42

11031N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 1 mg tablet, 42

11028K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 1.5 mg tablet, 42

11046J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 2 mg tablet, 42

11045H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

riociguat 2.5 mg tablet, 42

11052Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,681.06	Adempas [BN]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11261

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

selexipag 200 microgram tablet, 140

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12241G	1	2	0.00	7,696.74	Uptravi [JC]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority Required

11261

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**

- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

selexipag 800 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12253X	1	3	0.00	3,326.74	Uptravi [JC]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11195

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**

- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Authority Required

11193

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

(i) Hospitalisation due to worsening PAH;

(ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;

(iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;

(iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;

(v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

selexipag 200 microgram tablet, 60

12242H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	3,326.74	Uptravi [JC]

selexipag 400 microgram tablet, 60

12260G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 600 microgram tablet, 60

12248P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 800 microgram tablet, 60

12246M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 1 mg tablet, 60

12245L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12257D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 1.4 mg tablet, 60

12251T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

selexipag 1.6 mg tablet, 60

12264L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,326.74	Uptravi [JC]

SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required

18782

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18876

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13572

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

sildenafil 20 mg tablet, 90

9605M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	109.05	[a] SILDATIO PHT [RW]	[a] Sildenafil PHT APOTEX [TY]
				[a] SILDENAFIL PHT ARX [XT]	[a] Sildenafil Sandoz PHT 20 [SZ]

SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18748

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18854

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13569

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18749

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

sildenafil 20 mg tablet, 90

12138W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	109.05	[a] SILDATIO PHT [RW]	[a] Sildenafil PHT APOTEX [TY]
				[a] SILDENAFIL PHT ARX [XT]	[a] Sildenafil Sandoz PHT 20 [SZ]

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18782

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;

- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18876

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13572

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tadalafil 20 mg tablet, 56

1304P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	503.80	[a] Adcirca [LY]	[a] Tadalca [CR]
				[a] TADALIS 20 [LR]	

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18852

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;

- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18780

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15495

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tadalafil 20 mg tablet, 60

14229X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	539.13	Tadalis 20 [LR]

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18748

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and

- ECHO composite assessment; and

- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18854

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13569

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18749

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12150L	1	5	0.00	503.80	[a] Adcirca [LY]	[a] Tadalca [CR]
					[a] TADALIS 20 [LR]	

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18824

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:
- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:
- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:
- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:
(i) for why fewer than 3 tests are able to be performed on clinical grounds;
(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18872

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15463

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18884

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15525

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 60

14240L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	539.13	Tadalis 20 [LR]

DERMATOLOGICALS

ANTIPSORIATICS

ANTIPSORIATICS FOR SYSTEMIC USE

Psoralens for systemic use

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority Required (STREAMLINED)

10971

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; **OR**
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; **OR**
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

Population criteria:

- Patient must be aged 18 years or over.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12162D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
0.16666667000000002	6	0.00	*422.11	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority Required (STREAMLINED)

10989

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; **OR**
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12173Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
0.08333333	5	0.00	*215.67	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note No increase in the maximum quantity or number of units may be authorised.

Note Up to 2 additional repeats to that stated in this listing may be sought.

Authority Required (STREAMLINED)

12567

Chronic graft versus host disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment, **AND**
- Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition, **AND**

- Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12839R	0.16666667000000002	0	0.00	*422.11	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Current Medicare Benefits Schedule item numbers for extracorporeal photopheresis for the treatment of chronic graft-versus host disease are: 13761 and 13762.

Note A new treatment episode is considered to have begun when treatment with this drug/extracorporeal photopheresis follows a relapse of the condition. There is no limit on the number of new treatment cycles that may be commenced, but re-treatment following a relapse must not commence under 'Continuing treatment'.

Note A maximum quantity (vials) of 12 with 1 repeat prescription provides 24 doses of this drug. An additional 25th dose can be prescribed under this treatment phase by issuance of a further prescription made out for one vial with nil repeats. Alternatively, the 25th dose can be sought under the 'Continuing treatment' restriction. The 26th dose and onwards must be requested under the 'Continuing treatment' restriction.

Authority Required (STREAMLINED)

12579

Chronic graft versus host disease

Treatment Phase: Initial treatment in a treatment episode

Clinical criteria:

- The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; **OR**
- The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; **OR**
- The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed.

Treatment criteria:

- Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode, **AND**
- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12855N	1	1	0.00	2,431.16	Uvadex [TQ]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16906

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 300 mg/2 mL injection, 2 mL pen device

14940H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	444.11	Xolair [NV]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required (STREAMLINED)

16960

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

14911T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*437.68	Omlyclo [EW]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

7046

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 300 mg/2 mL injection, 2 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14930T	1	5	0.00	444.11	Xolair [NV]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Authority Required

7046

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11163M	2	5	0.00	*437.68	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14938F	2	5	0.00	*444.10	[a] Xolair [NV]

OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Authority Required

16906

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 150 mg/mL injection, 1 mL syringe

11175E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	2	0.00	*437.68	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14903J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	2	0.00	*444.10	[a] Xolair [NV]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Other anterior pituitary lobe hormones and analogues

PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19071

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) details of the proposed prescription(s); and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

11166Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	0	0.00	*559.72	Somavert [PF]

PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19071

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) details of the proposed prescription(s); and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19122

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11167R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	4,018.88	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11172B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	4,018.88	Somavert [PF]

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11174D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	4,018.88	Somavert [PF]

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

9261

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority Required (STREAMLINED)

9260

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

6423C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*1,748.70	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

6424D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*2,310.98	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

6425E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*2,630.76	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

17637
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11527Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*2,630.76	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

OCTREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)
17637
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11894B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,256.56	Sandostatin LAR [NV]

OCTREOTIDE

Authority Required (STREAMLINED)
9233
Acromegaly
Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority Required (STREAMLINED)
9289
Functional carcinoid tumour
Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

9232

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

6227R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
18	11	0.00	*271.32	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
				[a] Sandostatin 0.05 [NV]	

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

6228T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
18	11	0.00	*533.40	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
				[a] Sandostatin 0.1 [NV]	

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

6229W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
18	11	0.00	*1,919.58	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
				[a] Sandostatin 0.5 [NV]	

OCTREOTIDE

Authority Required (STREAMLINED)

9262

Acromegaly

Clinical criteria:

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority Required (STREAMLINED)

9313

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

9288

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10566D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*829.96	Sandostatin LAR [NV]

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10549F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,099.86	Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10558Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,256.56	Sandostatin LAR [NV]

PASIREOTIDE EMBONATE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority Required

19121

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; **OR**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be at least 18 years of age.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) details of the proposed prescription; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

d) a recent result of GH or IGF-1 levels must be provided.

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19069

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be at least 18 years of age.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10880P	2	5	0.00	*7,459.24	Signifor LAR [RJ]

pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10884W	2	5	0.00	*7,459.24	Signifor LAR [RJ]

pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10887B	2	5	0.00	*7,459.24	Signifor LAR [RJ]

CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority Required

10073

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have failed to respond to conventional therapy, **AND**
- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; **OR**
- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

cinacalcet 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9625N	2	5	0.00	*43.70	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 60 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9626P	2	5	0.00	*75.90	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9627Q	2	5	0.00	*107.22	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

CINACALCET

Authority Required (STREAMLINED)

10063

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

cinacalcet 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11891W	2	5	0.00	*43.70	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 60 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11889R	2	5	0.00	*75.90	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11888Q	2	5	0.00	*107.22	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority Required (STREAMLINED)

9604

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6221K NP	2	5	0.00	*124.44	Zithromax [PF]

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority Required (STREAMLINED)

9560

Mycobacterium avium complex infection

Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

Authority Required (STREAMLINED)

9622

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**

- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

rifabutin 150 mg capsule, 30

6195C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*556.12	Mycobutin [PF]

NP

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority Required (STREAMLINED)

15784

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority Required (STREAMLINED)

15782

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

6136Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	0.00	*250.70	[a] Cymevene [PB]	[a] GANCICLOVIR SXP [XC]

VALACICLOVIR

Authority Required (STREAMLINED)

9267

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

6280M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*217.24	[a] APX-Valaciclovir [TY]	[a] Valaciclovir RBX [RA]
		[B]14.05	*231.29	[a] Valtrex [RW]	

VALGANCICLOVIR

Authority Required (STREAMLINED)

15784

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority Required (STREAMLINED)

15782

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

9675F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11	5	0.00	*4,398.63	Valcyte [PB]

valganciclovir 450 mg tablet, 60

6357N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*504.50	[a] Valganciclovir Sandoz [SZ]	[a] Valganciclovir Viatris [AL]

Antivirals for treatment of HCV infections

GLECAPREVIR + PIBRENTASVIR

Authority Required

10268

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11337Q NP	1	3	0.00	16,895.91	Maviret [VE]

GLECAPREVIR + PIBRENTASVIR

Authority Required
7615
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11346E NP	1	2	0.00	16,895.91	Maviret [VE]

GLECAPREVIR + PIBRENTASVIR

Authority Required
7593
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11355P NP	1	1	0.00	16,895.91	Maviret [VE]

SOFOSBUVIR + VELPATASVIR

Authority Required
5969
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11144M NP	1	2	0.00	11,924.24	Epclusa [GI]

SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required
10248
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11659P NP	1	2	0.00	11,924.24	Vosevi [GI]

Other antivirals

MARIBAVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)
16806
Cytomegalovirus infection and disease
Clinical criteria:

- Patient must have received a hematopoietic stem-cell transplant; **OR**
- Patient must have received a solid-organ transplant, **AND**
- Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; **OR**
- Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, **AND**
- The treatment must be used as monotherapy for this condition under this restriction, **AND**
- Patient must not have previously demonstrated resistance to this drug, **AND**
- Patient must not have cytomegalovirus disease that involves the central nervous system, **AND**
- Patient must not have cytomegalovirus retinitis.

For the purpose of administering this restriction:
(i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level.
(ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet.
(iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.

maribavir 200 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14865J	4	1	0.00	*28,249.24	Livtencity [TK]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Authority Required
19124
Chronic Myelomonocytic Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) full blood examination report

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

azacitidine 100 mg injection, 1 vial

6100C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Authority Required (STREAMLINED)

13012

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

azacitidine 100 mg injection, 1 vial

13040H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	5	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13015

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

6138C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12439

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

12784W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13011

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

13033Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13010

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(b) full blood examination report.

azacitidine 100 mg injection, 1 vial

13038F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12983

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); **OR**
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The following information must be provided by the prescriber at the time of application:

(a) The patient's International Prognostic Scoring System (IPSS) score

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

azacitidine 100 mg injection, 1 vial

13039G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	0.00	*222.32	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority Required (STREAMLINED)

9287

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

Authority Required (STREAMLINED)

9223

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial

6249X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4	5	0.00	*585.08	[a] Caelyx [BX]	[a] Liposomal Doxorubicin SUN [RA]

PROTEIN KINASE INHIBITORS

Janus-associated kinase (JAK) inhibitors

RUXOLITINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19098

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ruxolitinib 5 mg tablet, 56

13244C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	2,305.49	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

13231J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	5	0.00	4,561.74	Jakavi [NV]

RUXOLITINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

13911

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ruxolitinib 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13239T	1	0	0.00	2,305.49	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13236P	1	0	0.00	4,561.74	Jakavi [NV]

Other protein kinase inhibitors

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19073

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and

(b) confirmation that the patient does not have progressive disease; and

(c) details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and

(d) details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

midostaurin 25 mg capsule, 112

11531X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	18,471.98	Rydapt [NV]

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13001

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition; **OR**
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11506N	1	2	0.00	9,260.61	Rydapt [NV]

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11699

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11518F	1	2	0.00	18,471.98	Rydapt [NV]

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD20 (Clusters of Differentiation 20) inhibitors

OBINUTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

19188

Lupus nephritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must not have demonstrated evidence of clinically significant worsening of the condition, confirmed by either: (i) an increase in urinary protein-to-creatinine ratio (UPCR); or (ii) a reduction in estimated glomerular filtration rate (eGFR) from baseline values, due to persisting active class III or IV lupus nephritis, based on 2 measurements taken 3 months apart, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The values for UPCR and eGFR, taken 3 months apart, used to determine the patient's response to treatment, must be documented in the patient's medical records.

obinutuzumab 1 g/40 mL injection, 40 mL vial

15516P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,348.48	Gazyva [RO]

OBINUTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

19168

Lupus nephritis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of active class III or IV lupus nephritis with or without class V disease, confirmed by renal biopsy, **AND**
- Patient must not have severe renal impairment, demonstrated by an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m^2, **AND**
- Patient must have/have had a urinary protein-to-creatinine ratio (UPCR) of at least 113 mg/mmol (equivalent to 1g/g) prior to initiation of treatment with this drug, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The baseline values of the eGFR and UCPR must be documented in the patient's medical records, as it will inform the basis for determining if worsening of the condition has occurred.

Authority Required

19169

Lupus nephritis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must not have sustained clinically significant, worsening from baseline values of either: (i) urinary protein-to-creatinine ratio (UPCR); and/or (ii) estimated glomerular filtration rate (eGFR), as determined by the treating physician, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The current values for UPCR and eGFR, used to determine the patient's response to treatment, must be documented in the patient's medical records.

obinutuzumab 1 g/40 mL injection, 40 mL vial

15509G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	4,348.48	Gazyva [RO]

RITUXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 500 mg/50 mL injection, 50 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13095F	2	1	0.00	*458.90	[a] Riximyo [SZ]	[a] Ruxience [PF]
					[a] Truxima [EW]	

RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13096G	3	0	0.00	*279.06	[a] Riximyo [SZ]	[a] Truxima [EW]

rituximab 100 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13109Y	6	0	0.00	*279.06	[a] Ruxience [PF]

OTHER ANTINEOPLASTIC AGENTS

Other antineoplastic agents

EFLORNITHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

17753

High-risk neuroblastoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease recurrence while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 27 cycles (based on 4 weeks per cycle) from the first dose of this drug, regardless of whether it was PBS/non-PBS-subsidised.

Treatment criteria:

- Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist; **OR**
- Must be treated by a medical practitioner under the direct supervision of either a: (i) paediatric oncologist, (ii) haematologist.

At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information.

The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription).

Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 m^2 to less than 0.5 m^2;

Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 m^2 to less than 0.75 m^2;

Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 m^2 to 1.5 m^2;

Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.

eflornithine 192 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14900F	3	2	0.00	*34,671.63	Ifinwil [NE]

EFLORNITHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16841

High-risk neuroblastoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have high-risk neuroblastoma according to a validated risk classification system, **AND**
- Patient must be in remission, with at least a partial response, at the end of multiagent, multimodality therapy for high-risk neuroblastoma, **AND**
- The treatment must be initiated after completing previous therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist.

Prior to initiating treatment with this drug, a complete blood count, liver function tests and baseline hearing assessments should be performed and documented in the patient's medical records.

At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information.

The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription).

Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 m^2 to less than 0.5 m^2;

Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 m^2 to less than 0.75 m^2;

Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 m^2 to 1.5 m^2;

Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.

Authority applications for initial treatment must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed PBS authority application form, relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) details of prior multiagent, multimodality therapy for high-risk neuroblastoma [date of commencement and duration of therapy]; and

(ii) the patient's BSA measurement.

eflornithine 192 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14910R	3	2	0.00	*34,671.63	Ifinwil [NE]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

14021

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**

- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14045

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 16

13099K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	9,409.24	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

14024

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14023

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 20

13103P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	11,749.24	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

14039

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14031

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 32

13105R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	18,769.24	Xpovio [TG]

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2733W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	0.00	*400.92	[a] Zarzio [SZ]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6292E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*400.90	[a] Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2747N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
4	11	0.00	*253.56	[a]	Zarzio [SZ]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

6291D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
2	11	0.00	*253.56	[a]	Nivestim [PF]

FILGRASTIM

Authority Required (STREAMLINED)

8674

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8667

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

8672

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

8668

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

8671

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

8696

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

8669

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

8670

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

8673

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5830W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*266.82	Nivestim [PF]

LIPEGFILGRASTIM

Authority Required (STREAMLINED)

9224

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

9322

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10931H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	0.00	1,165.49	Lonquex [TB]

PEGFILGRASTIM

Authority Required (STREAMLINED)

9235

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

9303

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

6363X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	11	0.00	90.76	[a] Pelgraz [OC]	[a] Ziextenzo [SZ]

Interferons

INTERFERON GAMMA-1B

Authority Required (STREAMLINED)

9639

Chronic granulomatous disease

Clinical criteria:

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

6148N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*1,768.80	Imukin [LM]

PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Pharmaceutical benefits that have the brand Pegasys (Ireland) can be substituted for Pegasys in the case of a shortage.

Authority Required (STREAMLINED)

17108

Chronic hepatitis C infection

Treatment criteria:

- Must be treated in an accredited treatment centre.

Population criteria:

- Patient must be at least 18 years of age
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Clinical criteria:

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6439X

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
NP	2	5	0.00	*1,706.52	a	Pegasys [XO]

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

15015G

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
NP	2	5	0.00	*2,408.38	a	Pegasys (Ireland) [XO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

6449K

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
NP	2	5	0.00	*1,968.50	a	Pegasys [XO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

15036J

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
NP	2	5	0.00	*2,514.16	a	Pegasys (Ireland) [XO]

Other immunostimulants

PLERIXAFOR

Authority Required (STREAMLINED)

9329

Mobilisation of haematopoietic stem cells

Clinical criteria:

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; **OR**
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**

- Patient must have failed previous stem cell collection; **OR**
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; **OR**
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

10084R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	0.00	1,178.78	[a] Plerixafor ARX [XT]	[a] PLERIXAFOR EUGIA [YG]

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14555

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

abatacept 250 mg injection, 1 vial

13705H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	0.00	*827.94	Orencia [BQ]

ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18169

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18272

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**

- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18274

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14488

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18273

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507
Severe active rheumatoid arthritis
Treatment Phase: First continuing treatment - balance of supply
Treatment criteria:
- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

abatacept 250 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9621J	1	0	0.00	282.14	Orencia [BQ]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)
9689
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)
9690
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

mycophenolate mofetil 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6208R	6	5	0.00	*129.06	[a] APO-Mycophenolate [TX] [a] Pharmacor Mycophenolate 250 [CR]	[a] Mycophenolate Sandoz [SZ]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)
9691
Management of renal allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)
9693
Management of cardiac allograft rejection
Treatment Phase: Management (initiation, stabilisation and review of therapy)
Clinical criteria:
- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

mycophenolate mofetil 500 mg tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6209T	6	5	0.00	*128.94	[a] ARX-MYCOPHENOLATE [XT]	[a] Ceptolate [AF]

6209T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
				[a] Mycophenolate GH [GQ]	[a] Mycophenolate Sandoz [SZ]
				[a] Pharmacor Mycophenolate 500 [CR]	

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

6364Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*399.57	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9692

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority Required (STREAMLINED)

9809

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

Clinical criteria:

- The condition must be proven by biopsy.

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

mycophenolate 180 mg enteric tablet, 120

6369F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*187.68	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

6370G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*280.82	[a] Mycophenolic Acid ARX [XT]	[a] MYCOTEX [CR]
				[a] Myfortic [NV]	

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**

- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12443X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	599.36	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12439Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*576.74	[a] Amgevita [XT]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15142Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

15140W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

15178W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

15154N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Amgevita [XT]	[a] Hadlima [RF]
				[a] Hyrimoz [SZ]	

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre

weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**

- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

15173N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	599.36	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

15202D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*576.74	[a] Amgevita [XT]

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13229G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12368Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13210G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12384T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	471.18	[a] Amgevita [XT]	[a] Hadlima [RF]
				[a] Hyrimoz [SZ]	

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

13292N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	5	0.00	599.36	[a]	Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12349Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
2	5	0.00	*576.74	[a]	Amgevita [XT]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12396K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9679K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	471.18	[a] Amgevita [XT]	[a] Hadlima [RF]
				[a] Hyrimoz [SZ]	

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12335F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	471.18	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9680L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	471.18	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17724

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**

- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17725

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17706

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 50 mg/mL injection, 4 x 1 mL syringes

9615C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	782.58	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

9641K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	782.58	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

13295R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*782.60	Enbrel [PF]

ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13326J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	782.58	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13332Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	782.58	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

ETANERCEPT

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17724

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17725

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17706

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

6367D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	395.92	Enbrel [PF]

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

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Authority Required

18994

Moderate to severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18995

Moderate to severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18992

Moderate to severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18993

Moderate to severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

infliximab 100 mg injection, 1 vial

9612X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required

19107

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19108

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

19152

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19176

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, or Continuing treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1 or 2 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

9674E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Authority Required

18774

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

18866

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

18849

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18775

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

18776

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under the Initial 1, 2 or 3 restrictions to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient treatment with this drug for this condition under the Continuing restriction to complete 24 weeks of treatment (8-weekly infusion regimen), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

9613Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18436

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18468

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18469

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18439

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18287

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18352

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

11158

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18470

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18437

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

8296

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

9617E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

18158

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

11489Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24

weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18164

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

11498E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required (STREAMLINED)

9632

Acute severe ulcerative colitis

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; **OR**
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

infliximab 100 mg injection, 1 vial

10057H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	1	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority Required

18391

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18431

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

11590B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

Authority Required (STREAMLINED)

19011

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight will be authorised.

An increase in maximum repeats to 5 may be requested.

infliximab 100 mg injection, 1 vial

11450P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the

total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14505

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11483J	3	2	0.00	*590.07	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

9472

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11515C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break

in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete.

There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required

12059

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11797X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to

provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14585

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

infliximab 100 mg injection, 1 vial

13700C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	2	0.00	*590.07	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required (STREAMLINED)

18868

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11396T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required (STREAMLINED)

12074

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11796W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required (STREAMLINED)

14689

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required (STREAMLINED)

14723

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11488P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	3	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority Required (STREAMLINED)

9602

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required (STREAMLINED)

9584

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11595G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration

- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required (STREAMLINED)

19150

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

infliximab 100 mg injection, 1 vial

11432Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*977.29	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

14718

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority Required

14707

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

14667

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

infliximab 100 mg injection, 1 vial

13778E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least

12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

14502

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14623

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14544

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14548

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

infliximab 100 mg injection, 1 vial

13724H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18502

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic scoreless than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18196

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18355

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; **OR**
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9754

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

10184B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18165

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18345

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18267

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14548

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18343

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

infliximab 100 mg injection, 1 vial

6397Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

18340

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18162

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18263

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18462

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

9559

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14705

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

infliximab 100 mg injection, 1 vial

6448J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18191

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18192

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18194

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9111

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18441

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9068

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

6496X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	202.85	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

Interleukin inhibitors

ANAKINRA

Authority Required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

- Must be treated by a rheumatologist or in consultation with a rheumatologist; **OR**
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for conditions other than CAPS.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

10263E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,195.88	Kineret [ZO]

SILTUXIMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

12585

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; **OR**
- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

Note The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.

Details of these criteria are presented in Table 2 of the following literature article:

Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. *Blood* 2017; 129(12): 1646-1657.

Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.

Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

Authority Required

12594

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

siltuximab 100 mg injection, 1 vial

12930M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	0.00	*1,607.80	Sylvant [RJ]

siltuximab 400 mg injection, 1 vial

12934R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	4	0.00	*6,283.44	Sylvant [RJ]

TOCILIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Authority Required

18174

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 80 mg/4 mL injection, 4 mL vial

12787B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

12766X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12805Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17713

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13311N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*177.66	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13312P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13338B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

14179

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 200 mg/10 mL injection, 10 mL vial

13329M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*426.72	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13323F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*839.98	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14485

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13696W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*177.66	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13716X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13731Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority Required

18348

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority Required

18280

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilzumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

tocilizumab 80 mg/4 mL injection, 4 mL vial

12811G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

12795K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12810F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

14179

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13315T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*346.08	Actemra [RO]

TOCILIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

14148

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; **OR**
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Authority Required

14091

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

14085

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

10570

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

tocilizumab 80 mg/4 mL injection, 4 mL vial

1419Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1423X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1464C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17712

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17714

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17729

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tocilizumab 80 mg/4 mL injection, 4 mL vial

10068X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10079L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10060L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline

measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18275

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18172

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18276

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14488

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18346

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

9671B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

9672C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9673D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	424.61	Actemra [RO]

TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority Required

18180

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18177

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18282

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9386

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18279

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

9380

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

10073E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	94.21	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10071C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	217.98	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10078K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	424.61	Actemra [RO]

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required

19171

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19172

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19149

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1 or Initial 2), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

ustekinumab 130 mg/26 mL injection, 26 mL vial

13804M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,292.16	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a

cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Authority Required

18825

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18856

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18785

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11164N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,292.16	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

16958

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority Required

16939

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Authority Required

16866

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

ustekinumab 130 mg/26 mL injection, 26 mL vial

13255P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,292.16	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

Calcineurin inhibitors

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9831

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

Caution Careful monitoring of patients is mandatory.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

6109M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	67.34	Sandimmun [NV]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9764

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9695

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

15361

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9694

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; **OR**
- Patient must be intolerant to treatment with steroids and cytostatic drugs; **OR**
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9742

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); **OR**
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist.

Caution Careful monitoring of patients is mandatory.

ciclosporin 10 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6232B	2	5	0.00	*87.64	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6352H	4	5	0.00	*101.40	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6353J	4	5	0.00	*200.04	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6354K	4	5	0.00	*398.00	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6125J	4	5	0.00	*1,312.40	Neoral [NV]

TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9697

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

Caution Careful monitoring of patients is mandatory.

tacrolimus 500 microgram capsule, 100

6328C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*116.32	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 0.5 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 500 microgram modified release capsule, 30

9681M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*88.28	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10875J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*179.94	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

6216E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*223.40	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 1 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 1 mg modified release capsule, 60

9682N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*137.74	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10879N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*497.32	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11920J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	0.00	*693.76	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

6217F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*544.38	[a] Pharmacor Tacrolimus 5 [CR]	[a] Prograf [LL]
					[a] Tacrograf [RW]	[a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9683P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*789.70	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

Monoclonal antibodies

ALEMTUZUMAB

Authority Required (STREAMLINED)

9636

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10243D	5	0	0.00	*51,464.69	Lemtrada [GZ]

ALEMTUZUMAB

Authority Required (STREAMLINED)

9589

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10246G	3	0	0.00	*30,898.50	Lemtrada [GZ]

ANIFROLUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19216

Systemic lupus erythematosus

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019, **AND**
- Patient must have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points, **AND**
- Patient must be currently receiving hydroxychloroquine, with treatment received for at least 12 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving immunosuppressant medication, with treatment received for at least 12 weeks, with either: (i) minimum dose of methotrexate 20 mg per week, (ii) azathioprine 100 mg per day, (iii) mycophenolate 1,000 mg per day unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving prednisolone or equivalent of at least 7.5 mg per day, with treatment received for at least 4 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus, **AND**
- The treatment must not be used in combination with obinutuzumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.

Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.

If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg

per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

(a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;

(b) details (date and score) of the completed SLEDAI-2K score sheet;

(c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);

(d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19096

Systemic lupus erythematosus

Treatment Phase: Continuing or recommencement of treatment (within 12 months of a treatment break)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must be responding to treatment if they have received less than 12 months of treatment with this drug for this condition; **OR**
- Patient must have attained a Lupus Low Disease Activity State (LLDAS) and maintained this state while on treatment, **AND**
- The treatment must not be used in combination with obinutuzumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

Lupus Low Disease Activity State (LLDAS) is defined as:

(a) Total SLEDAI-2K of not greater than 4, with no major activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever); and

(b) No new features of lupus disease activity compared with the previous assessment, and

(c) Physician Global Assessment (PGA) of not greater than 1, and

(d) Current prednisolone (or equivalent) dose of not greater than 7.5 mg daily, and

(e) Well tolerated standard maintenance doses of anti-malarial and immunosuppressive drugs are allowed.

Where retreatment with anifrolumab after a break in PBS-subsidised treatment with anifrolumab is being sought, the date of cessation of the previous treatment course with anifrolumab must be included in the application. Recommencement of treatment with anifrolumab for severe SLE is within 12 months from the date that treatment was ceased.

Note SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

Note PGA can be accessed via Petri 2005 N Engl J Med 353: 2550-8.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

anifrolumab 300 mg/2 mL injection, 2 mL vial

14189T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,497.24	Saphnelo [AP]

NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority Required (STREAMLINED)

13625

Clinically definite relapsing-remitting multiple sclerosis

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

natalizumab 150 mg/mL injection, 2 x 1 mL syringes

13820J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	638.33	Tysabri [BD]

natalizumab 300 mg/15 mL injection, 15 mL vial

9624M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	638.33	Tysabri [BD]

OCRELIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

9523

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority Required (STREAMLINED)

9635

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11237K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	0	0.00	*16,705.60	Ocrevus [RO]

ocrelizumab 920 mg/23 mL injection, 23 mL vial

15113K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	16,705.60	Ocrevus SC [RO]

UBLITUXIMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

9523

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Ublituximab 150 mg/6 mL injection, 6 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15187H	4	0	0.00	*15,493.24	Briumvi [FW]

UBLITUXIMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

9635

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

Ublituximab 150 mg/6 mL injection, 6 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15197W	3	0	0.00	*11,632.23	Briumvi [FW]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

18805

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18906

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to

treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18863

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18806

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

18759

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

18807

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

vedolizumab 300 mg injection, 1 vial

10415E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	2,851.67	Entyvio [TK]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Authority Required

18760

Severe Crohn disease

Treatment Phase: Initial 4 (additional dose at week 10)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in this treatment cycle, **AND**
- Patient must have received 3 doses of initial treatment under either: (i) Initial 1, (ii) Initial 2, (iii) Initial 3, **AND**
- Patient must not have achieved an adequate response to this drug after a total of 3 doses of initial treatment under either: (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

A maximum quantity and number of repeats to provide for an additional dose of this drug consisting of one vial of 300 mg, with one dose to be administered at week 10, will be authorised.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patient must be assessed as having an inadequate response to the drug after completing an initial infusion regimen at 0, 2, and 6 weeks and prior to 10 weeks.

vedolizumab 300 mg injection, 1 vial

14614E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	2,851.67	Entyvio [TK]

VEDOLIZUMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3

biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required

15933

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15910

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15844

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15923

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15909

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10398G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	2,851.67	Entyvio [TK]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

19210

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; **OR**
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- The treatment must be initiated in combination with standard of care antibiotic, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore and the date of assessment; and

(b) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

Authority Required

19112

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 (Recommencement of treatment after a break in targeted therapy)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must be initiated in combination with standard of care antibiotic, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of the most recent targeted therapy for this condition [date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

Authority Required

19113

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 14 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (recommencement of treatment after a break in targeted therapy) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Authority Required

19155

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

vedolizumab 300 mg injection, 1 vial

14679N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	2,851.67	Entyvio [TK]

Mammalian target of rapamycin (mTOR) kinase inhibitors

EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9691

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9693

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

everolimus 250 microgram tablet, 60

6459Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*325.26	[a] Certican [NV]	[a] Everocan [CR]

everolimus 500 microgram tablet, 60

6460B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*560.88	[a] Certican [NV]	[a] Everocan [CR]

everolimus 750 microgram tablet, 60

6461C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*1,640.48	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

9582H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	0.00	*2,170.92	[a] Certican [NV]	[a] Everocan [CR]

SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

9914

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*620.28	Rapamune [PF]

sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*1,224.28	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*970.22	Rapamune [PF]

sirolimus 2 mg tablet, 100

6457W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*2,399.36	Rapamune [PF]

Complement inhibitors

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14754

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; **OR**
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of kidney transplant if applicable (especially if required due to aHUS);

(7) An inclusion of the individual consequences of recurrent disease, if applicable;

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

A maximum of up to 80 weeks of eculizumab treatment (or 104 weeks if switching C5 inhibitors during the course of initial and continuing treatment) is allowed under this restriction, however an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14805

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; **OR**
- Patient must have severe TMA-related neurological impairment; **OR**
- Patient must have severe TMA-related gastrointestinal impairment; **OR**
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; **OR**
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); **OR**
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14799

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS if applicable;

(6) A history of multiple episodes of aHUS following the treatment break, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

Authority Required

14793

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14753

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised ravulizumab (all phases) - loading dose

Clinical criteria:

- Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 24 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

eculizumab 300 mg/30 mL injection, 30 mL vial

10194M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	5,407.84	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17651

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

Clinical criteria:

- Patient must be planning pregnancy; **OR**
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17626

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**

- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority Required

17602

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**

- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Authority Required

17697

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17693

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eculizumab 300 mg/30 mL injection, 30 mL vial

12899X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	5	0.00	*32,200.86	Soliris [XI]

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14781

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**

- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;

(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

eculizumab 300 mg/30 mL injection, 30 mL vial

10182X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	5,407.84	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.

Note This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17675

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

eculizumab 300 mg/30 mL injection, 30 mL vial

12864C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	5,407.84	Soliris [XI]

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Note Services Australia will contact the prescriber by telephone after a written application has been submitted.

Authority Required

14792

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14750

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement - Balance of Supply

Clinical criteria:

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

eculizumab 300 mg/30 mL injection, 30 mL vial

10192K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	0.00	5,407.84	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17684

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - initial 1 (new patient) induction doses

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**

- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17673

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)

Clinical criteria:

- Patient must be planning pregnancy; **OR**
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17630

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Switching from PBS-subsidised pegcetacoplan or iptacopan - induction doses

Clinical criteria:

- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

eculizumab 300 mg/30 mL injection, 30 mL vial

12896R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
8	0	0.00	*42,918.04	Soliris [XI]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17647

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under 'Initial 1' (new untreated patient) or 'Initial 2' (switching from a Complement 5 (C5) inhibitor), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17598

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First continuing treatment', 'Return' criteria, or 'Grandfather' treatment restrictions, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

Authority Required

17599

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement 1 (Complement 5 (C5) inhibitor inexperienced patients)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2025, **AND**
- Patient must not have received any treatment for this condition prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a diagnosis of PNH established by flow cytometry prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had PNH granulocyte clone size equal to or greater than 10% prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Authority Required

17622

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement 2 (Complement 5 (C5) inhibitor experienced patients)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2025, **AND**
- Patient must have had PNH granulocyte clone size equal to or greater than 10% within the last 3 months prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating non-PBS-subsidised treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must have been in combination with one C5 inhibitor for a period of 4 weeks during initiation of therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13197N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	4,393.10	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17683

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab post pregnancy or from one of the PBS-subsidised therapies for this condition, for reasons other than post pregnancy

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)' criteria; **OR**
- Patient must have received prior PBS-subsidised treatment with at least one drug listed for this condition and must be returning to pegcetacoplan treatment for reasons other than post pregnancy, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)
For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13191G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,393.10	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.
Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

17623

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from a Complement 5 (C5) inhibitor)

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)
(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13196M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,393.10	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17601

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new untreated patient)

Clinical criteria:

- Patient must not have received prior treatment with any of the PBS-subsidised therapies listed for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

15117P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,393.10	Empaveli [ZO]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18135

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18423

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Non-loading/maintenance doses)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**

- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18238

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18137

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 March 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

15234T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15254W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18132

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18131

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication ('bridging therapy for gMG').

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18237

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**

- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18133

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15263H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15259D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14748

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Balance of Supply - maintenance doses

Clinical criteria:

- Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note Services Australia will contact the prescriber by telephone after a written application has been submitted.

Authority Required

18260

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 72 weeks of ravulizumab treatment in total under this restriction; **OR**
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of kidney transplant if applicable (especially if required due to aHUS);

(7) An inclusion of the individual consequences of recurrent disease, if applicable;

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18262

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; **OR**
- Patient must have severe TMA-related neurological impairment; **OR**
- Patient must have severe TMA-related gastrointestinal impairment; **OR**
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; **OR**
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); **OR**
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18153

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18155

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply of a C5 inhibitor treatment was commenced, the patient: (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample not confounded by any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing C5 inhibitor treatment; (iv) had clinical features of active organ damage or impairment, **AND**
- Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients;

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay;

(6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised C5 inhibitor treatment;

(7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised C5 inhibitor treatment;

(8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for the balance of the current treatment phase. 8 weeks of treatment and up to 2 repeats according to the specified dosage in the approved Product Information (PI) may be sought.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

13786N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

13784L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note See the following article/website for details on Expanded Disability Status Scale (EDSS): https://www.ncbi.nlm.nih.gov/books/NBK222389/.

Authority Required

16368

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a neurologist; **OR**
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ravulizumab 300 mg/3 mL injection, 3 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14771K	1	2	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14776Q	1	2	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note See the following article/website for details on Expanded Disability Status Scale (EDSS): https://www.ncbi.nlm.nih.gov/books/NBK222389/.

Authority Required

17055

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Initial treatment - loading dose

Clinical criteria:

- Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG), **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must have experienced at least one relapse in the last 12 months while receiving treatment with rituximab; **OR**
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; **OR**

- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a neurologist; **OR**
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

The authority application must be in writing and must include all of the following:

(1) details of the proposed authority prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the patient's Expanded Disability Status Scale (EDSS) score; and

(ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ravulizumab 300 mg/3 mL injection, 3 mL vial

14746D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

14745C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18134

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have received a loading dose of this drug for this indication; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15235W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15264J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17631

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)
(ii) Platelets ($x10^9$/L)
(iii) White Cell Count ($x10^9$/L)
(iv) Reticulocytes ($x10^9$/L)
(v) Neutrophils ($x10^9$/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority Required

17629

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)
(ii) Platelets ($x10^9$/L)
(iii) White Cell Count ($x10^9$/L)
(iv) Reticulocytes ($x10^9$/L)
(v) Neutrophils ($x10^9$/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17609

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12895Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12897T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

18351

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Initial (new patient) loading dose

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients;

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;

(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Authority Required

18350

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised eculizumab (all phases) - loading dose

Clinical criteria:

- Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; **OR**

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommencement of treatment' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18283

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS if applicable;

(6) A history of multiple episodes of aHUS following the treatment break, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Two authority prescription forms will be required to cover for the 26 weeks of recommencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

ravulizumab 300 mg/3 mL injection, 3 mL vial

13791W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

13802K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	24,154.35	Ultomiris [XI]

RAVULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17605

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**

- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17610

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; **OR**

- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17606

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17630

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Switching from PBS-subsidised pegcetacoplan or iptacopan - induction doses

Clinical criteria:

- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12841W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	6,623.36	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12901B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	24,154.35	Ultomiris [XI]

ZILUCOPLAN

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18232

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18378

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18129

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18128

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15285L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	21,444.29	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15315C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	29,570.29	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15284K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	41,707.86	Zilbrysq [UC]

ZILUCOPLAN

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18319

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15302J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	21,444.29	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15304L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	29,570.29	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15294Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	41,707.86	Zilbrysq [UC]

Neonatal fragment crystallizable receptor (FcRn) inhibitors

ROZANOLIXIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18232

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:
(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);
(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].
If the application is submitted through HPOS form upload or mail, it must include the following:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18378

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).
The authority application must be via the Online PBS Authorities System, or in writing and must include:
(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).
If the application is submitted through HPOS form upload or mail, it must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18129

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18789

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15375F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
18	2	0.00	*219,238.80	Rystiggo [UC]

ROZANOLIXIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18319

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**

- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15362M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	18	1	0.00	*219,238.80	Rystiggo [UC]

Other immunosuppressants

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19067

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12071H	1	3	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12060R	1	3	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12020P	1	3	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14631C	1	3	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12068E	1	3	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

13782

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12984J	1	2	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12980E	1	2	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12980E					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12986L	1	2	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14583M	1	2	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12993W	1	2	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

13813

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12038N	1	1	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12050F	1	1	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12011E	1	1	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14609X	1	1	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12037M	1	1	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

14362

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13642B	1	2	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13658W	1	2	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13657T	1	2	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14582L	1	2	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13660Y	1	2	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

17414

Untreated multiple myeloma

Treatment Phase: Triple combination therapy consisting of daratumumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with daratumumab obtained through the PBS for the treatment of transplant ineligible, newly diagnosed multiple myeloma, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 5 mg capsule, 21

15103X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

15079P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

15073H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

15105B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

15096M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19062

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and

(3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and

(4) details of the basis of the diagnosis of progressive disease or failure to respond; and

(5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13805

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

9642L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

9643M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

9644N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14610Y	1	0	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9645P	1	0	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19119

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and

(2) confirmation of ineligibility for prior stem cell transplant; and

(3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority Required

13787

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

14624Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	809.51	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19076

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13804

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11966T	1	2	0.00	526.12	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11969Y	1	2	0.00	686.38	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11965R	1	2	0.00	824.79	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19079

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple

myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13811

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 14

12058P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	267.68	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 14

12004T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	347.81	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 14

12069F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	417.01	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 14

14615F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	0.00	534.61	Lenalide [JU]

lenalidomide 25 mg capsule, 14

12018M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	542.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19065

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report; and

(c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

19066

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**

- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

lenalidomide 5 mg capsule, 21

2798G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

2796E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

18932

Relapsed or refractory follicular lymphoma

Clinical criteria:

- The treatment must be in combination with rituximab and tafasitamab; **OR**
- The treatment must be in combination with tafasitamab.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

lenalidomide 5 mg capsule, 21

15418L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	396.90	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

15485B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	517.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

15488E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	620.91	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

15486C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	797.29	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority Required

13746

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and

(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13755

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pomalidomide 1 mg capsule, 21

13814C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	421.17	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 2 mg capsule, 21

13811X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	743.56	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	1,108.36	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	1,461.39	Pomalidomide Sandoz [SZ]	Pomolide [JU]

POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority Required

13757

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority Required

13768

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

pomalidomide 1 mg capsule, 14

13813B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	283.86	Pomolide [JU]

pomalidomide 2 mg capsule, 14

13812Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	498.79	Pomolide [JU]

pomalidomide 3 mg capsule, 14

12668R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	743.56	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 4 mg capsule, 14

12661J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	988.33	Pomalidomide Sandoz [SZ]	Pomolide [JU]

THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Authority Required (STREAMLINED)

9290

Multiple myeloma

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

thalidomide 50 mg capsule, 28

6469L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	0	0.00	*1,110.64	Thalomid [BQ]

thalidomide 100 mg capsule, 28

9684Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	0	0.00	*1,110.62	Thalomid [BQ]

MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

Authority Required (STREAMLINED)

9562

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority Required (STREAMLINED)

9525

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority Required (STREAMLINED)

9638

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority Required (STREAMLINED)

9606

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11194E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*645.08	Sintetica Baclofen Intrathecal [BZ]

BACLOFEN

Note Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

9488

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority Required (STREAMLINED)

9637

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority Required (STREAMLINED)

9489

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority Required (STREAMLINED)

9524

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

6284R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	0	0.00	*802.44	[a] Bacthecal [DZ]	[a] Lioresal Intrathecal [NV]

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

11128Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	802.45	[a] Sintetica Baclofen Intrathecal [BZ]

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

PAMIDRONATE DISODIUM

Authority Required (STREAMLINED)

9234

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

6288Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	68.50	Pamisol [PF]

PAMIDRONATE DISODIUM

Authority Required (STREAMLINED)

9234

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority Required (STREAMLINED)

9335

Multiple myeloma

Authority Required (STREAMLINED)

9315

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

6289B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	0.00	96.13	Pamisol [PF]

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

14729

Adjuvant management of breast cancer

Population criteria:

- Patient must be post-menopausal.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

13772W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	58.96	[a] DEZTRON [DZ]	[a] Zoledronate-DRLA 4 [RZ]
				[a] Zoledronic Acid Accord [OC]	

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

9268

Multiple myeloma

Authority Required (STREAMLINED)

9328

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority Required (STREAMLINED)

9304

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

Authority Required (STREAMLINED)

9317

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

6371H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	11	0.00	58.96	[a] APO-Zoledronic Acid [TX]	[a] DEZTRON [DZ]
				[a] Zoledronate-DRLA 4 [RZ]	[a] Zoledronic Acid Accord [OC]
				[a] Zometa [SA]	

Other drugs affecting bone structure and mineralization

BUROSUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13377

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a documented confirmation of PHEX pathogenic variant; **OR**
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

18953

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

burosumab 10 mg/mL injection, 1 mL vial

13163T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	4,048.24	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

13136J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	8,047.24	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

13154H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	12,046.24	Crysvita [KO]

BUROSUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18982

Tumour-induced osteomalacia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not be a candidate for curative surgical resection as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Prescribers should, where possible, rule out all other non-hereditary forms of FGF-23 related hypophosphataemia such as Fanconi syndrome, iron-infusion associated hypophosphataemia or post renal transplantation hypophosphataemia, prior to initiating patients on burosumab treatment for this condition.

Authority Required

18950

Tumour-induced osteomalacia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

18952

Tumour-induced osteomalacia

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have, prior to initiating treatment with this drug, a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not have been a candidate for curative surgical resection, prior to initiating treatment with this drug, as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have had demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour prior to initiating treatment with this drug, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

burosumab 10 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15479Q	1	5	0.00	4,048.24	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15500T	1	5	0.00	8,047.24	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15493K	1	5	0.00	12,046.24	Crysvita [KO]

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

Other drugs for disorders of the musculo-skeletal system

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14459

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; **OR**
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**

- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. *Muscle & Nerve* 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. *PLoS ONE* 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. *American Journal of Respiratory and Critical Care Medicine* 166(1), pp 111-117

The National Hearth Foundation of Australia has 6MWT test standardised instructions and recording forms located at: https://www.heartonline.org.au/resources/documents-and-links#exercise

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. *Muscle & Nerve* 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. *Neurology* April (15 Supplement) P4.452

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13045N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18094

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**

- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Failure to gain weight appropriate for age,

(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

18078

Spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

Treatment criteria:

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

Note Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13064N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18077

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in a child

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,

(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

18101

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

Treatment criteria:

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

Note Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13111C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18073

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**

- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:
i) Onset before 6 months of age; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Defined signs and symptoms of type II SMA are:
i) Onset between 6 and 18 months; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Weakness in trunk righting/derotation; or
v) Hypotonia; or
vi) Absence of deep tendon reflexes; or
vii) Failure to gain weight appropriate for age; or
viii) Any active chronic neurogenic changes; or
ix) A compound muscle action potential below normative values for an age-matched child.
Defined signs and symptoms of type IIIa SMA are:
i) Onset between 18 months and 3 years of age; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Application for authorisation of initial treatment must be in writing and must include:
(a) details of the proposed prescription; and
(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
(i) specification of SMA type (I, II or IIIa); and
(ii) sign(s) and symptom(s) that the patient has experienced; and
(iii) patient's age at the onset of sign(s) and symptom(s).

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

11472T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

15069

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist

medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**

- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

11476B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18110

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

12176W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

14433

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13091B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

15112

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

14090N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,549.24	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18076

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

14096X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,549.24	Spinraza [BD]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18087

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

i) Onset between 6 and 18 months; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Weakness in trunk righting/derotation; or

v) Hypotonia; or

vi) Absence of deep tendon reflexes; or

vii) Failure to gain weight appropriate for age; or

viii) Any active chronic neurogenic changes; or

ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

i) Onset between 18 months and 3 years of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.
Application for authorisation of initial treatment must be in writing and must include:
(a) details of the proposed prescription; and
(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
(i) specification of SMA type (I, II or IIIa); and
(ii) sign(s) and symptom(s) that the patient has experienced; and
(iii) patient's age at the onset of sign(s) and symptom(s).
The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
(iv) 2 years of age and older weighing 20 kg or more: 5 mg
In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:
1 unit where (i) applies;
2 units where (ii) applies;
3 units where (iii) applies;
3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12610Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15986

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

14639L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

Authority Required

15095

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12609P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the next authority application after this application, continue treatment through the 'Treatment phase: Continuing treatment' under the indication: 'Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)'.

Authority Required

18357

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA

Clinical criteria:

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

Population criteria:

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:

1. Rolls from side to side on back;

2. Child holds head erect for at least 3 seconds unsupported;

3. Sitting, but with assistance;

4. Sitting without assistance:

(a) Child sits up straight with the head erect for at least 10 seconds;

(b) Child does not use arms or hands to balance body or support position.

5. Hands and knees crawling:

(a) Child alternately moves forward or backwards on hands and knees;

(b) The stomach does not touch the supporting surface;

(c) There are continuous and consecutive movements at least 3 in a row.

6. Standing with assistance:

(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;

(b)The body does not touch the stable object, and the legs support most of the body weight;

(c) Child thus stands with assistance for at least 10 seconds.

7. Standing alone:
(a) Child stands in upright position on both feet (not on the toes) with the back straight;
(b) The leg supports 100% of the child's weight;
(c) There is no contact with a person or object;
(d) Child stands alone for at least 10 seconds.
8. Walking with assistance:
(a) Child is in an upright position with the back straight;
(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
(c) One leg moves forward while the other supports part of the body weight;
(d) Child takes at least 5 steps in this manner.
9. Walking alone:
(a) Child takes at least 5 steps independently in upright position with the back straight;
(b) One leg moves forward while the other supports most of the body weight;
(c) There is no contact with a person or object.

Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i).

Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.

The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:
1 unit where (i) applies;
2 units where (ii) applies;
3 units where (iii) applies;
3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12959C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18118

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA)

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The condition must be pre-symptomatic, **AND**

- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13647G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18090

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

14647X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,891.13	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18306

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 5 mg tablet, 28

15274X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18369

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Population criteria:

- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

risdiplam 5 mg tablet, 28

15298E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18479

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 5 mg tablet, 28

15308Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18307

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must be between 2 and 18 years of age and weigh 20 kg or more.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

i) Onset between 6 and 18 months; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Weakness in trunk righting/derotation; or

v) Hypotonia; or

vi) Absence of deep tendon reflexes; or

vii) Failure to gain weight appropriate for age; or

viii) Any active chronic neurogenic changes; or

ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

i) Onset between 18 months and 3 years of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and
(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
(i) specification of SMA type (I, II or IIIa); and
(ii) sign(s) and symptom(s) that the patient has experienced; and
(iii) patient's age at the onset of sign(s) and symptom(s).

risdiplam 5 mg tablet, 28

15321J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.
Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

18356

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:
(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
(ii) Proximal weakness,
(iii) Hypotonia,
(iv) Absence of deep tendon reflexes,
(v) Failure to gain weight appropriate for age,
(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13632L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	7	0.00	*32,574.90	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. *Muscle & Nerve* 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. *PLoS ONE* 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. *American Journal of Respiratory and Critical Care Medicine* 166(1), pp 111-117

The National Hearth Foundation of Australia has 6MWT test standardised instructions and recording forms located at: https://www.heartonline.org.au/resources/documents-and-links#exercise

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. *Muscle & Nerve* 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. *Neurology* April (15 Supplement) P4.452

Authority Required

14420

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; **OR**
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13646F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,574.90	Evrysdi [RO]

risdiplam 5 mg tablet, 28

15290R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

Authority Required

14392

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13659X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,574.90	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18308

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC)
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,

(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 5 mg tablet, 28

15296C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18225

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Failure to gain weight appropriate for age,

(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 5 mg tablet, 28

15328R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,346.98	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

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Authority Required

18197

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,

(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13639W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,574.90	Evrysdi [RO]

NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

FOSLEVODOPA + FOSCARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

16883

Advanced Parkinson disease

Treatment criteria:

- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

14888N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*5,025.92	Vyalev [VE]

FOSLEVODOPA + FOSCARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

16972

Advanced Parkinson disease

Treatment criteria:

- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must require continuous administration of foslevodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2,400 mg of foslevodopa.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

14915B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
8	5	0.00	*10,002.60	Vyalev [VE]

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

10363

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2000 mg of levodopa.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9744W	8	5	0.00	*11,585.24	Duodopa [VE]

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

10161

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11910W	4	5	0.00	*5,817.24	Duodopa [VE]

Dopamine agonists

APOMORPHINE

Authority Required (STREAMLINED)

11445

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9640J	36	5	0.00	*6,078.84	Movapo [TD]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10971K	36	5	0.00	*8,066.40	Movapo PFS [TD]

APOMORPHINE

Authority Required (STREAMLINED)

10830

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11083H	18	5	0.00	*7,476.54	Apomine Solution for Infusion [IT]

Apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15132K	18	5	0.00	*7,476.54	MOVAPO POD [TD]

APOMORPHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

10830

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11475Y	20	5	0.00	*2,637.24 [a]	Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

11688E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	20	5	0.00	*2,637.24	[a] Apomine Intermittent [IT]

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority Required (STREAMLINED)

9490

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; **OR**
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

clozapine 50 mg/mL oral liquid, 100 mL

11415T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	149.64	Versacloz [DU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

9490

Schizophrenia

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:

- Patient must be non-responsive to other neuroleptic agents; **OR**
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

6101D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*68.74	Clopine 25 [DU] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

6417R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*124.66	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

9632Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	149.64	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

6102E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	0	0.00	*225.64	Clopine 100 [DU] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6418T	2	0	0.00	*442.04	Clopine 200 [DU]	Clozitor [JU]

PSYCHOANALEPTICS

ANTIDEPRESSANTS

Other antidepressants

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16477

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 8 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14787G	8	0	0.00	*2,408.25	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16419

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 12 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14798W	4	5	0.00	*3,584.89	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16460

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 4 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14811M	4	5	0.00	*1,231.61	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16470

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 8 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14814Q	4	5	0.00	*2,408.25	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16454

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 24 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14823E	8	0	0.00	*7,114.81	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16422

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 16 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14831N	8	0	0.00	*4,761.53	Spravato [JC]

OTHER NERVOUS SYSTEM DRUGS

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

VUTRISIRAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16446

Hereditary transthyretin amyloidosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing, **AND**
- Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; **OR**
- Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV).

Treatment criteria:

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

Population criteria:

- Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy
- Patient must be at least 18 years of age.

PND scores in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage I - Sensory disturbances but preserved walking capability;

Stage II - Impaired walking capacity but able to walk without stick or crutches;

Stage IIIA - Walking with help of one stick or crutch;

Stage IIIB - Walking with help of two sticks or crutches;

Stage IV - Confined to wheelchair or bedridden.

FAP stage in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage 1 - Unimpaired ambulation;

Stage 2 - Assistance with ambulation required;

Stage 3 - Wheelchair-bound or bedridden.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

16434

Hereditary transthyretin amyloidosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not be permanently bedridden; **OR**
- Patient must not be receiving end-of-life care.

Treatment criteria:

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Vutrisiran 25 mg/0.5 mL injection, 0.5 mL syringe

14829L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	114,171.20	Amvuttra [WM]

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

benralizumab 30 mg/mL injection, 1 mL pen device

11999M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	3,194.69	Fasenra Pen [AP]

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19128

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

benralizumab 30 mg/mL injection, 1 mL pen device

11996J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	3,194.69	Fasenra Pen [AP]

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19130

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the eosinophil count and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19082

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

benralizumab 30 mg/mL injection, 1 mL pen device

11997K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	0.00	3,194.69	Fasenra Pen [AP]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note It is recommended that an application for continuing treatment is submitted at the 28 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Authority Required

19137

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; **OR**
- Patient must have a fractional exhaled nitric oxide of at least 20 ppb in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment, blood eosinophil count or fractional exhaled nitric oxide measurement must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE, blood eosinophil or the fractional exhaled nitric oxide result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Authority Required

19091

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**

- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE, blood eosinophil or fractional exhaled nitric oxide result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

14960J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	1,659.10	[a] Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

14965P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	1,659.10	[a] Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au);

the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note It is recommended that an application for continuing treatment is submitted at the 28 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

19137

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; **OR**
- Patient must have a fractional exhaled nitric oxide of at least 20 ppb in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment, blood eosinophil count or fractional exhaled nitric oxide measurement must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE, blood eosinophil or the fractional exhaled nitric oxide result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Authority Required

19091

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE, blood eosinophil or fractional exhaled nitric oxide result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

14962L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
	1	7	0.00	1,659.10	[a]	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

14999K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
	1	7	0.00	1,659.10	[a]	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

17073

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
14977G	1	0	0.00	1,659.10	[a]	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
15034G	1	0	0.00	1,659.10	[a]	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17073

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

15000L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	1,659.10	[a] Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

15042Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	1,659.10	[a] Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19136

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12316F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,659.10	Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12294C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,659.10	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19132

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**

- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;

AND

(ii) treatment with oral corticosteroids as outlined in the clinical criteria.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19133

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have each of: (i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12310X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	8	0.00	1,659.10	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19181

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19213

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**

- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12313C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	8	0.00	1,659.10	Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

17009

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) maintenance oral corticosteroid dose; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

Authority Required

17113

Uncontrolled severe asthma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025, **AND**

- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate to determine whether the patient has achieved or sustained an adequate response to non-PBS subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been at least 28 weeks

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an

interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(b) IgE, blood eosinophils or fractional exhaled nitric oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and

(c) date of commencing non-PBS-subsidised treatment with this drug for this condition.

(d) If applicable, maintenance oral corticosteroid dose; and

(e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or

(f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

15012D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	5	0.00	1,659.10	[a]	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

15043R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	5	0.00	1,659.10	[a]	Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17009

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) maintenance oral corticosteroid dose; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

Authority Required

17113

Uncontrolled severe asthma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate to determine whether the patient has achieved or sustained an adequate response to non-PBS subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been at least 28 weeks

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(b) IgE, blood eosinophils or fractional exhaled nitric oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and

(c) date of commencing non-PBS-subsidised treatment with this drug for this condition.

(d) If applicable, maintenance oral corticosteroid dose; and

(e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or

(f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

15022P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	2	0.00	1,659.10	a	Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

15033F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	2	0.00	1,659.10	a	Dupixent [SW]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response

to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

mepolizumab 100 mg/mL injection, 1 mL pen device

12043W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	1,605.34	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19200

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for this condition, **AND**

- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with the initial PBS authority application, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

The following must be provided in each continuing PBS authority application and be documented in the patient's medical records:

details of the current number and severity of exacerbations compared to baseline levels provided in the initial authority application of this treatment cycle including:

(i) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(ii) number of moderate exacerbations requiring treatment with antibiotics; and

(iii) number of severe exacerbation(s) which required hospitalisation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

19166

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved, prior to commencing non-PBS-subsidised treatment with this drug for this condition, adequate control with at least 3 months of optimised triple inhaled therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with this authority application, if they received at least 24 weeks of treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; AND

(ii) details of therapy with a combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement, and duration of therapy prior to commencing non-PBS-subsidised treatment with this drug for this condition); AND

(iii) the baseline exacerbation history which includes:

details of the number and severity of COPD exacerbations experienced in the 12 months immediately prior to commencement of this drug as non-PBS-subsidised therapy for this condition, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation; AND

(iv) the assessment of response to treatment where applicable (for patients who have received at least 24 weeks of treatment), which includes:

details of the current number and severity of COPD exacerbations, compared with the baseline information supplied in this authority application, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction.

In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

mepolizumab 100 mg/mL injection, 1 mL pen device

15508F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,605.34	Nucala [GK]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19128

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

mepolizumab 100 mg/mL injection, 1 mL pen device

12052H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,605.34	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

Authority Required

19092

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Initial treatment (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**

- Patient must have had at least a 12-month break from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing treatment with this drug in this treatment cycle, **AND**
- Patient must not have achieved adequate control with at least 3 months of an optimised triple inhaler therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing treatment with this drug in this treatment cycle, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to starting treatment in this treatment cycle are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; and

(ii) details of the optimised triple inhaler therapy with the combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement and duration of therapy); and

(iii) details of the number and severity of COPD exacerbation(s) experienced in the 12 months prior to commencing treatment with this drug in this treatment cycle including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbation(s) which required hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction. In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

mepolizumab 100 mg/mL injection, 1 mL pen device

15515N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	0.00	1,605.34	Nucala [GK]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19139

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the eosinophil count and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19184

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

mepolizumab 100 mg/mL injection, 1 mL pen device

12051G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	1,605.34	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

Authority Required

19198

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

Clinical criteria:

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; **OR**
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; **OR**
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

Population criteria:

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated

(b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

The authority application must be made in writing and must include:

(a) details of the proposed prescription,

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),

(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,

(d) details (date and treatment) of nasal polyp surgery; or

(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,

(f) the eosinophil count and date,

(g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13865

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

Population criteria:

- Patient must be at least 18 years of age.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

mepolizumab 100 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13242Y	1	5	0.00	1,605.34	Nucala [GK]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19163

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Authority Required

19141

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses

for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10956P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	6	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 300 mg/2 mL injection, 2 mL pen device

14912W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	444.11	Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17012

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment - Balance of Supply in a patient aged 6 to 12 years

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 28 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 28 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11958J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11932B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	223.46	Omlyclo [EW]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses

of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

11825J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	223.46	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14883H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	226.67	[a] Xolair [NV]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11826K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14939G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	117.96	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

19135

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The following information must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

14919F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	116.35	Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL syringe

14927P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	223.46	Omlyclo [EW]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 300 mg/2 mL injection, 2 mL pen device

14951X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	444.11	Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 300 mg/2 mL injection, 2 mL pen device

14953B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	444.11	Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11840E	1	5	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14921H	1	5	0.00	117.96	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
11864K	1	5	0.00	223.46	[a]	Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
14928Q	1	5	0.00	226.67	[a]	Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17086

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11952C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

17084

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 150 mg/mL injection, 1 mL syringe

11953D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	223.46	Omlyclo [EW]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

17102

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

14882G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	116.35	Omlyclo [EW]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**

- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10110D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	7	0.00	116.35	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14904K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	117.96	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 150 mg/mL injection, 1 mL syringe

10122R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	223.46	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14923K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	226.67	[a] Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19163

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose,

and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Authority Required

19141

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 150 mg/mL injection, 1 mL syringe

10968G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	0.00	223.46	Omlyclo [EW]

TEZEPELUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For copies of the ACQ and the calculation sheets please contact AstraZeneca Medical Information on 1800 805 342.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19094

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater

than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**

- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiating treatment with this drug that has past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the month prior to initiating this drug, AND

(b) while receiving optimised asthma therapy in the 12 months prior to initiating this drug, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Authority Required

19199

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing biological medicine treatment for severe asthma; **OR**
- Patient must have each of: i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating treatment with a biological medicine for severe asthma, ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

Authority Required

19095

Uncontrolled severe asthma

Treatment Phase: Grandfathering arrangements - Transitioning from non-PBS to PBS-subsidised supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this biological medicine for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have had a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiation of non-PBS subsidised treatment with this drug for this condition that had past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the month prior to starting treatment with this drug, AND

(b) while receiving optimised asthma therapy in the 12 months prior to starting treatment with this drug, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15363N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	1,721.02	Tezspire [AP]

TEZEPELUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For copies of the ACQ and the calculation sheets please contact AstraZeneca Medical Information on 1800 805 342.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19093

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug and should be conducted within 4 weeks of the last dose of biological medicine.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15364P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,721.02	Tezspire [AP]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority Required (STREAMLINED)

9624

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

9591

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; **OR**
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; **OR**
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; **OR**
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

9592

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

6120D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,540.22	Pulmozyme [RO]

MANNITOL

Authority Required (STREAMLINED)

9527

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

9593

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

mannitol 40 mg powder for inhalation, 280 capsules

2008Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*1,838.44	Bronchitol [HT]

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17970

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17937

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12938Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17846

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17971

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84

13266F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17772

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17770

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56

14279M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Trikafta [VR]

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

14280N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Trikafta [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16971

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 1 month or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 13.4 mg granules, 56 sachets

14936D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	20,355.49	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority Required

16928

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 1 month or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 13.4 mg granules, 56 sachets

14902H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	20,355.49	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16878

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority Required

16876

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

14165M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

11097C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11109Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10175M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,355.49	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16844

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

16845

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

14147N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

14158E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

14157D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

14169R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,355.49	Kalydeco [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17934

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17842

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11463H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16,971.12	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17967

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17933

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11464J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16,971.12	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17765

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17763

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets

13795C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,971.12	Orkambi [VR]

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11841F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,971.12	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11848N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,971.12	Orkambi [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17844

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**

- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be at least 12 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and

(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17935

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11833T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	19,001.74	Symdeko [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17968

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17969

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**

- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11834W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	19,001.74	Symdeko [VR]

VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17932

Cystic fibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to vanzacaftor/tezacaftor/deutivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Population criteria:

- Patient must be at least 6 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17769

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

vanzacaftor 4 mg + tezacaftor 20 mg + deutivacaftor 50 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15211N	1	5	0.00	21,424.24	Alyftrek [VR]

vanzacaftor 10 mg + tezacaftor 50 mg + deutivacaftor 125 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15204F	1	5	0.00	21,424.24	Alyftrek [VR]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority Required

7385

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**

- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 90 mg tablet, 30

11558H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

11557G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

11511W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

7385

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 125 mg dispersible tablet, 28

11241P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

11244T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11232E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required

7375

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority Required

7374

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 90 mg tablet, 30

11545P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

11546Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

11496C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

7375

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority Required

7374

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 125 mg dispersible tablet, 28

6499C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

6500D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

9600G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required (STREAMLINED)

9302

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority Required (STREAMLINED)

9222

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority Required (STREAMLINED)

9258

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

deferasirox 90 mg tablet, 30

11548T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*100.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 125 mg dispersible tablet, 28

11236J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*626.70	Deferasirox Juno [JU]

deferasirox 180 mg tablet, 30

11510T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*190.32	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 250 mg dispersible tablet, 28

11238L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*137.64	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

11547R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*371.40	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11243R	6	2	0.00	*381.66	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERIPRONE

Authority Required (STREAMLINED)

9286

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority Required (STREAMLINED)

9228

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 100 mg/mL oral liquid, 250 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9638G	5	5	0.00	*1,010.84	Ferriprox [EU]

deferiprone 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6416Q	3	5	0.00	*1,204.92	Ferriprox [EU]

DEFERIPRONE

Authority Required (STREAMLINED)

9623

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority Required (STREAMLINED)

9590

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 1 g tablet, 50

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11724C	6	5	0.00	*2,360.64	Ferriprox [EU]

DESFERRIOXAMINE

Authority Required (STREAMLINED)

9696

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

desferrioxamine mesilate 500 mg injection, 10 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6113R	40	5	0.00	*5,604.44	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 2 g injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6270B	60	5	0.00	*2,664.24	DBL Desferrioxamine Mesilate [PF]

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority Required (STREAMLINED)

9762

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**

- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 500 mg chewable tablet, 2 x 45

9635D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*353.28	Fosrenol [TK]

lanthanum 750 mg chewable tablet, 6 x 15

9636E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*528.74	Fosrenol [TK]

lanthanum 1 g chewable tablet, 6 x 15

9637F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*594.08	Fosrenol [TK]

SEVELAMER

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority Required (STREAMLINED)

9762

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9620H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*339.56	[a] Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

11838C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*297.82	[a] ARX-SEVELAMER [XT]	[a] Sevelamer Lupin [GQ]

SUCROFERRIC OXYHYDROXIDE

Authority Required (STREAMLINED)

9762

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10230K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*716.44	Velphoro [CS]

Other therapeutic products

DIFELIKEFALIN

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

Authority Required

15211

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist; **OR**
- Must be treated by a medical practitioner in consultation with a nephrologist.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14106K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	570.84	Korsuva [CS]

DIFELIKEFALIN

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

Authority Required

15171

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**
- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug/dialysis related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

(i) optimisation of dialysis;

(ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);

(iii) patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14110P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	570.84	Korsuva [CS]

Highly Specialised Drugs Program (Public Hospital)

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ALIMENTARY TRACT AND METABOLISM

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

Enzymes

PEGUNIGALSIDASE ALFA

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19015

Fabry disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one of: (i) documented deficiency of alpha-galactosidase enzyme activity in blood, (ii) presence of genetic mutations known to result in deficiency of alpha-galactosidase enzyme activity, **AND**
- Patient must be male with Fabry-related renal disease confirmed by at least one of the following: (i) abnormal albuminuria of more than 20 mcg/min, as determined by 2 separate samples at least 24 hours apart, (ii) abnormal proteinuria of more than 150 mg/24 hours, (iii) albumin:creatinine ratio greater than upper limit of normal in 2 separate samples at least 24 hours apart, (iv) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must be female with Fabry-related renal disease confirmed by at least one of the following: (i) proteinuria of more than 300 mg/24 hours with clinical evidence of progression, (ii) renal disease due to long-term accumulation of glycosphingolipids in the kidneys; **OR**
- Patient must have Fabry-related cardiac disease confirmed by at least one of the following: (i) left ventricular hypertrophy, as evidenced by cardiac magnetic resonance imaging (MRI) or echocardiogram data, in the absence of hypertension, (ii) significant life-threatening arrhythmia or conduction defect, (iii) late gadolinium enhancement or a low T1 on cardiac MRI; **OR**
- Patient must have Fabry-related either: (i) ischaemic disease, (ii) cerebrovascular disease as shown on objective testing with no other cause or risk factors identified; **OR**
- Patient must have Fabry-related uncontrolled chronic pain despite the use of recommended doses of appropriate analgesia and antiseizure medications for peripheral neuropathy; **OR**
- Patient must have significant Fabry-related gastrointestinal symptoms despite the use of the recommended doses of appropriate pharmacological therapies, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

If hypertension is present in patients relying their eligibility on Fabry-related cardiac disease, the prescriber must treat it optimally for at least 6 months prior to submitting the first PBS authority application.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18930

Fabry disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18929

Fabry disease

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Fabry disease therapy)

Clinical criteria:

- Patient must have previously received treatment with Enzyme Replacement Therapy for this condition funded under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19045

Fabry disease

Treatment Phase: Switching from PBS-subsidised migalastat

Clinical criteria:

- Patient must have received prior treatment with PBS-subsidised migalastat for this condition, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have failed to demonstrate clinical improvement or stabilisation of this condition with previous PBS-subsidised treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of Fabry disease.

Confirmation of eligibility for treatment with diagnostic reports including the confirmed mutations must be documented in the patient's medical records.

At the time of authority application, prescribers must request the appropriate number of vials, based on the weight of the patient, to provide sufficient drug for 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Pegunigalsidase alfa 20 mg/10 mL injection, 10 mL vial

15469E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,842.40	ELFABRIO [EU]

Various alimentary tract and metabolism products

NITISINONE

Note No increase in the maximum number of repeats may be authorised.

Authority Required

19055

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19058

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**

- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18959

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

Population criteria:

- Patient must be less than 18 years of age.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nitisinone 4 mg/mL oral liquid, 90 mL

15426X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	4,149.58	Orfadin [FK]

NITISINONE

Note No increase in the maximum number of repeats may be authorised.

Authority Required

19053

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of HT-1 based on the presence of succinylacetone in either: (i) urine, (ii) blood, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine, **AND**
- Patient must not be suffering from any other severe or life-threatening medical condition, including complications or sequelae of HT-1, that might compromise the effectiveness of treatment with this drug or where the long-term prognosis is unlikely to be altered by treatment with this drug.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results must be conducted no more than 12 months prior to the date of authority application and documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19057

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Grandfather arrangement (transition from LSDP-funded Hereditary Tyrosinaemia type 1 therapy)

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition under the Australian Government's Life Saving Drugs Program (LSDP) prior to 1 August 2026, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**

- Must be treated in a centre with expertise in genetic metabolic disorders.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Confirmation of eligibility for treatment with diagnostic reports including the blood and/or urine test results at baseline, must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18958

Hereditary tyrosinaemia type 1 (HT-1)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must not have developed another life threatening/severe disease where long term prognosis is unlikely to be influenced by this drug, **AND**
- The treatment must be in combination with dietary restriction of tyrosine and phenylalanine.

Treatment criteria:

- Must be treated by a physician with expertise in the management of HT-1, **AND**
- Must be treated in a centre with expertise in genetic metabolic disorders.

At the time of authority application, the prescriber must request the appropriate quantity units of appropriate strength(s), based on the weight of the patient, to provide sufficient drug for up to 4 weeks of treatment at the dosage regimen specified in the approved Therapeutic Goods Administration (TGA) Product Information (PI). Up to 5 repeats will be authorised to provide for a total of 24 weeks of treatment.

A separate authority prescription form must be completed for each strength requested.

Liver function tests (LFT), Full blood count (FBC) and Alpha-fetoprotein (AFP) results confirming eligibility for continuing treatment must be documented in the patient's medical records.

Prescribers must state the patient's body weight with every authority application, and document it in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nitisinone 2 mg capsule, 60

15482W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,168.91	Orfadin [FK]

nitisinone 5 mg capsule, 60

15460Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,272.01	Orfadin [FK]

nitisinone 10 mg capsule, 60

15435J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,946.38	Orfadin [FK]

nitisinone 20 mg capsule, 60

15501W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	7,366.56	Orfadin [FK]

TEDUGLUTIDE

Note Special Pricing Arrangements apply.

Authority Required

11999

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment, **AND**
- The treatment must provide no more than the balance of up to 12 months of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11808L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	19,710.60	Revestive [TK]

TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18198

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; **OR**
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline; **OR**
- The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above.

Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

From 1 September 2021

Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:

(i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and

(ii) the current value (observed over a 4 week timeframe)

Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.

Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

11794R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	19,710.60	Revestive [TK]

TEDUGLUTIDE

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note

A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18986

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

Clinical criteria:

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the 4 weeks prior to commencing this drug, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:

(i) for a patient of any age, the mean number of days of parenteral support per week,

(ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to commencing this drug. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11793Q	1	11	0.00	19,710.60	Revestive [TK]

BLOOD AND BLOOD FORMING ORGANS

ANTIHEMORRHAGICS

VITAMIN K AND OTHER HEMOSTATICS

Other systemic hemostatics

AVATROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18297

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15375

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14054

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15340

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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avatrombopag 20 mg tablet, 30

13313Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,601.06	Doptelet [ZO]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

15173

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 25 mg tablet, 28

14120E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	5	0.00	*3,684.36	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18209

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; **OR**
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

eltrombopag 25 mg tablet, 28

14144K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	3	0.00	*3,684.36	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

15173

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than 50 x 10^9/L, haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than 1 x 10^9/L for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14112R	3	5	0.00	*7,368.72	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18209

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; **OR**
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

eltrombopag 50 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14121F	3	3	0.00	*7,368.72	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16455

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 25 mg tablet, 28

14128N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	5	0.00	*3,684.36	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16455

Severe aplastic anaemia

Treatment Phase: First line treatment

Clinical criteria:

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eltrombopag 50 mg tablet, 28

14131R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	5	0.00	*7,368.72	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18210

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14129

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13327

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14127

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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eltrombopag 25 mg tablet, 28

5825N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,228.12	Revolade [NV]

ELTROMBOPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18210

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14129

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13327

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14127

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

eltrombopag 50 mg tablet, 28

5826P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,456.24	Revolade [NV]

ROMIPLOSTIM

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18405

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14099

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; **OR**
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; **OR**

- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13396

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14149

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

Clinical criteria:

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; **OR**
- Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

romiplostim 250 microgram injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9696H	1	5	0.00	494.12	Nplate [AN]

romiplostim 500 microgram injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9698K	1	5	0.00	988.24	Nplate [AN]

ANTIANEMIC PREPARATIONS

OTHER ANTIANEMIC PREPARATIONS

Other antianemic preparations

DARBEPOETIN ALFA

Authority Required (STREAMLINED)

6294
Anaemia associated with intrinsic renal disease
Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5637Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*224.36	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5638R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*422.54	Aranesp [AN]

darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL pen device

5645D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*422.56	Aranesp SureClick [AN]

darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5639T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*578.08	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5640W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*701.66	Aranesp [AN]

darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL pen device

5646E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*701.60	Aranesp SureClick [AN]

darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5641X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*867.48	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5642Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,018.64	Aranesp [AN]

darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL pen device

5647F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*1,018.64	Aranesp SureClick [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes

5644C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,340.82	Aranesp [AN]

darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL pen device

5648G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*1,340.88	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL pen device

5649H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*1,651.12	Aranesp SureClick [AN]

darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes

5651K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,651.16	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes

5643B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*2,460.18	Aranesp [AN]

darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL pen device

5650J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	8	5	0.00	*2,460.16	Aranesp SureClick [AN]

EPOETIN ALFA

Authority Required (STREAMLINED)
6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5720C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*420.20	Eprex 3000 [JC]

epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

5721D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*535.14	Eprex 4000 [JC]

epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5713Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*2,442.22	Eprex 20,000 [JC]

epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

5714R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*175.98	Eprex 1000 [JC]

epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

5715T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*666.22	Eprex 5000 [JC]

epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

5719B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*325.64	Eprex 2000 [JC]

epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5716W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*790.84	Eprex 6000 [JC]

epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

5717X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,025.72	Eprex 8000 [JC]

epoetin alfa 40 000 units/mL injection, 1 mL syringe

5718Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*790.12	Eprex 40,000 [JC]

epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes

5722E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*1,241.44	Eprex 10000 [JC]

EPOETIN LAMBDA

Authority Required (STREAMLINED)

6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

9670Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*399.20	Novicrit [SZ]

epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

9587N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*508.38	Novicrit [SZ]

epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

9589Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	2	5	0.00	*632.92	Novicrit [SZ]

epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9668W					
NP	2	5	0.00	*167.20	Novicrit [SZ]

epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9591T					
NP	2	5	0.00	*751.32	Novicrit [SZ]

epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9594Y					
NP	2	5	0.00	*974.44	Novicrit [SZ]

epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9596C					
NP	2	5	0.00	*1,179.42	Novicrit [SZ]

epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9669X					
NP	2	5	0.00	*309.34	Novicrit [SZ]

METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA

Authority Required (STREAMLINED)

6294

Anaemia associated with intrinsic renal disease

Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5794Y					
NP	2	5	0.00	*221.00	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5795B					
NP	2	5	0.00	*368.34	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5796C					
NP	2	5	0.00	*536.36	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5797D					
NP	2	5	0.00	*693.68	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5798E					
NP	2	5	0.00	*803.12	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5799F					
NP	2	5	0.00	*1,151.90	Mircera [RO]

methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5800G					
NP	2	5	0.00	*1,991.30	Mircera [RO]

CARDIOVASCULAR SYSTEM

ANTIHYPERTENSIVES

OTHER ANTIHYPERTENSIVES

Antihypertensives for pulmonary arterial hypertension

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18836

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18741

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13575

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ambrisentan 5 mg tablet, 30

5607D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	1,219.75	[a] Ambrisentan Viatris [AL]	[a] PULMORIS [XT]
				[a] Volibris [ZE]	

ambrisentan 10 mg tablet, 30

5608E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	1,219.75	[a] Ambrisentan Viatris [AL]	[a] Cipla Ambrisentan [ZU]
				[a] PULMORIS [XT]	[a] Volibris [ZE]

AMBRISENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension

- Congenital heart disease
- Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

ambrisentan 5 mg tablet, 30

12212R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1,219.75	[a] Ambrisentan Viatris [AL]	[a] PULMORIS [XT]
					[a] Volibris [ZE]	

ambrisentan 10 mg tablet, 30

12186J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	1,219.75	[a] Ambrisentan Viatris [AL]	[a] Cipla Ambrisentan [ZU]
					[a] PULMORIS [XT]	[a] Volibris [ZE]

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bosentan 62.5 mg tablet, 60

12134P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
					[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12425

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

Clinical criteria:

- Patient must be receiving PBS-subsidised treatment with this PAH agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

bosentan 62.5 mg tablet, 60

12140Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18738

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18833

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13571

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

bosentan 62.5 mg tablet, 60

5618Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

bosentan 125 mg tablet, 60

5619R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan GH [GQ]	[a] Bosentan RBX [RA]
				[a] Bosentan Viatris [AL]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;

- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 62.5 mg tablet, 60

12145F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan RBX [RA]	

BOSENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

bosentan 125 mg tablet, 60

12149K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	117.53	[a] Bosentan APO [GX]	[a] BOSENTAN DR.REDDY'S [RI]
				[a] Bosentan GH [GQ]	[a] Bosentan RBX [RA]
				[a] Bosentan Viatris [AL]	

EPOPROSTENOL

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18208

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13491

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13577

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18401

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18859

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH is established through a prior PBS authority application

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO functional class II status with at least one of the following: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18802

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing the prostanoid agent in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13506

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

epoprostenol 500 microgram injection, 1 vial

10130E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	0.00	*998.40	Veletri [JC]

epoprostenol 1.5 mg injection, 1 vial

10117L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
30	5	0.00	*1,779.90	Veletri [JC]

ILOPROST

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18403

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

13491

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13577

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18294

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

18859

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy that has a prostanoid in the combination (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of PAH is established through a prior PBS authority application

Clinical criteria:

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO functional class II status with at least one of the following: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, (iv) dual combination therapy with an endothelin receptor antagonist plus a phosphodiesterase-5 inhibitor, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18802

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing the prostanoid agent in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13506

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules

5751Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	349.59	Ventavis [BN]

MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18836

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18741

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13575

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

macitentan 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10136L	1	5	0.00	2,299.25	Opsumit [JC]

MACITENTAN

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18752

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; this combination therapy is treating a patient with at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18737

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will

be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13497

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18743

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due

to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

macitentan 10 mg tablet, 30

12147H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	2,299.25	Opsumit [JC]

MACITENTAN + TADALAFIL

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

16457

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must be dual combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil; **OR**
- The treatment must be part of triple combination therapy as a fixed dose combination consisting of: (i) macitentan, (ii) tadalafil, (iii) one prostanoid.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (dual or triple therapy, excluding selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application.

This treatment is not PBS-subsidised for the use as initial therapy

For the purposes of PBS subsidy, a prostanoid is one of: (a) epoprostenol, (b) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination' therapy.

Note If this authority application is to continue combination therapy, but with a change in prostanoid, the 'Initial 3 - change' treatment phase restriction of the new drug outlines the continuing eligibility criteria of that new drug.

Authority Required

16433

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (triple therapy with selexipag)

Clinical criteria:

- The treatment must be part of triple combination therapy consisting of: (i) macitentan, (ii) tadalafil, (iii) selexipag.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised macitentan and tadalafil as part of combination therapy (triple therapy with selexipag) where macitentan and tadalafil and their doses in the combination remain unchanged from the previous authority application.

This treatment is not PBS-subsidised for the use as initial therapy

The authority application for selexipag must be approved prior to the authority application for this agent.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Macitentan 10 mg + tadalafil 40 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14785E	1	5	0.00	2,552.08	Opsynvi [JC]

RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

Note Special Pricing Arrangements apply.

Authority Required

18200

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; **OR**
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn*sec*cm^{-5} measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn*sec*cm^{-5} measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the results from the 3 tests below, to establish baseline measurements, where available:

(i) RHC composite assessment, and

(ii) ECHO composite assessment, and

(iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

(1) RHC plus ECHO composite assessments;

(2) RHC composite assessment plus 6MWT;

(3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

(1) ECHO composite assessment plus 6MWT;

(2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15271

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

(1) RHC plus ECHO composite assessments plus 6MWT;

(2) RHC plus ECHO composite assessments;

(3) RHC composite assessment plus 6MWT;

(4) ECHO composite assessment plus 6MWT;

(5) RHC composite assessment only;

(6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15272

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated in a centre with expertise in the management of CTEPH.

Population criteria:

- Patient must be at least 18 years of age.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

riociguat 500 microgram tablet, 42

11001B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 1 mg tablet, 42

10976Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 1.5 mg tablet, 42

10989J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 2 mg tablet, 42

10984D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 2.5 mg tablet, 42

11002C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

RIOCIGUAT

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

Note Special Pricing Arrangements apply.

Authority Required

18215

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:
(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.
(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:
- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:
- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:
- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:
(i) for why fewer than 3 tests are able to be performed on clinical grounds;
(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.
(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.
(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13514

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

Clinical criteria:

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13502

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

riociguat 500 microgram tablet, 42

11040C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 1 mg tablet, 42

11054T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 1.5 mg tablet, 42

11047K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 2 mg tablet, 42

11038Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

riociguat 2.5 mg tablet, 42

11057Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	1,631.82	Adempas [BN]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11261

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

selexipag 200 microgram tablet, 140

12258E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	7,647.50	Uptravi [JC]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Authority Required

11261

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment - dose titration

Clinical criteria:

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

selexipag 800 microgram tablet, 60

12266N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	3,277.50	Uptravi [JC]

SELEXIPAG

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11195

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

Clinical criteria:

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; **OR**
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an

endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**

- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Population criteria:

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.

Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Authority Required

11193

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

(i) Hospitalisation due to worsening PAH;

(ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;

(iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;

(iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;

(v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

selexipag 200 microgram tablet, 60

12247N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 400 microgram tablet, 60

12235Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 600 microgram tablet, 60

12263K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 800 microgram tablet, 60

12249Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 1 mg tablet, 60

12259F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 1.2 mg tablet, 60

12252W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 1.4 mg tablet, 60

12240F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

selexipag 1.6 mg tablet, 60

12265M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,277.50	Uptravi [JC]

SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18782

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18876

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:

Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13572

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

sildenafil 20 mg tablet, 90

9547L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	95.81	[a] SILDATIO PHT [RW]	[a] Sildenafil PHT APOTEX [TY]
				[a] SILDENAFIL PHT ARX [XT]	[a] Sildenafil Sandoz PHT 20 [SZ]

SILDENAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18748

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:
- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:
- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18854

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13569

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18749

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**

- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

sildenafil 20 mg tablet, 90

12144E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	95.81	[a] SILDATIO PHT [RW]	[a] Sildenafil PHT APOTEX [TY]
				[a] SILDENAFIL PHT ARX [XT]	[a] Sildenafil Sandoz PHT 20 [SZ]

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18782

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;

- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18876

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13572

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tadalafil 20 mg tablet, 56

1308W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	475.54	[a] Adcirca [LY]	[a] Tadalca [CR]
				[a] TADALIS 20 [LR]	

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18852

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 1 - New patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;

- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18780

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment 2 - Change of treatment

Clinical criteria:

- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents:
Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent,

subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15495

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tadalafil 20 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14281P	1	5	0.00	509.51	Tadalis 20 [LR]

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18748

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18854

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13569

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18749

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11229

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 56

12151M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	475.54	[a] Adcirca [LY]	[a] Tadalca [CR]
				[a] TADALIS 20 [LR]	

TADALAFIL

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority Required

18824

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; this combination therapy is treating a patient with at least class WHO functional class III PAH; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes:

- Idiopathic PAH
- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18872

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; prior monotherapy has been inadequate - the patient has at least WHO functional class III PAH; **OR**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate - the patient has WHO functional class IV PAH.

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15463

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18884

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

Clinical criteria:

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; **OR**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

Treatment criteria:

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application; **OR**
- Patient must be undergoing continuing treatment with dual combination therapy consisting of endothelin receptor antagonist with phosphodiesterase-5 inhibitor where one drug was prescribed as a non-PBS benefit, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

Note If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15525

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

Clinical criteria:

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); **OR**
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phoshodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

tadalafil 20 mg tablet, 60

14271D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	509.51	Tadalis 20 [LR]

DERMATOLOGICALS

ANTIPSORIATICS

ANTIPSORIATICS FOR SYSTEMIC USE

Psoralens for systemic use

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority Required (STREAMLINED)

10988

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; **OR**
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12154Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
0.08333333	5	0.00	*198.49	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

Authority Required (STREAMLINED)

10985

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; **OR**
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; **OR**
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

Population criteria:

- Patient must be aged 18 years or over.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12156T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
0.16666667000000002	6	0.00	*396.99	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note No increase in the maximum quantity or number of units may be authorised.

Note Up to 2 additional repeats to that stated in this listing may be sought.

Authority Required (STREAMLINED)

12531

Chronic graft versus host disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment, **AND**
- Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**

- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition, **AND**
- Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12854M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
0.16666667000000002	0	0.00	*396.99	Uvadex [TQ]

METHOXSALEN

Caution This drug is for ex vivo administration and must not to be injected directly into the patient.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Current Medicare Benefits Schedule item numbers for extracorporeal photopheresis for the treatment of chronic graft-versus host disease are: 13761 and 13762.

Note A new treatment episode is considered to have begun when treatment with this drug/extracorporeal photopheresis follows a relapse of the condition. There is no limit on the number of new treatment cycles that may be commenced, but re-treatment following a relapse must not commence under 'Continuing treatment'.

Note A maximum quantity (vials) of 12 with 1 repeat prescription provides 24 doses of this drug. An additional 25th dose can be prescribed under this treatment phase by issuance of a further prescription made out for one vial with nil repeats. Alternatively, the 25th dose can be sought under the 'Continuing treatment' restriction. The 26th dose and onwards must be requested under the 'Continuing treatment' restriction.

Authority Required (STREAMLINED)

12546

Chronic graft versus host disease

Treatment Phase: Initial treatment in a treatment episode

Clinical criteria:

- The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; **OR**
- The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; **OR**
- The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed.

Treatment criteria:

- Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25th dose) of a treatment episode, **AND**
- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.

methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials

12876Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	2,381.92	Uvadex [TQ]

OTHER DERMATOLOGICAL PREPARATIONS

OTHER DERMATOLOGICAL PREPARATIONS

Agents for dermatitis, excluding corticosteroids

OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16906

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 300 mg/2 mL injection, 2 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14895Y	1	2	0.00	418.14	Xolair [NV]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

7046

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 300 mg/2 mL injection, 2 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14913X	1	5	0.00	418.14	Xolair [NV]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required (STREAMLINED)

16905

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14946P	2	5	0.00	*411.96	Omlyclo [EW]

OMALIZUMAB

Note Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

Note A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Authority Required

7046

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11168T	2	5	0.00	*411.96	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14937E	2	5	0.00	*418.14	[a] Xolair [NV]

OMALIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Authority Required

16906

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a clinical immunologist; **OR**
- Must be treated by an allergist; **OR**
- Must be treated by a dermatologist; **OR**
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

Clinical criteria:

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

1) a H2 receptor antagonist (150 mg twice per day); or

2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or

3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:

(i) demonstration of failure to achieve an adequate response to standard therapy; and

(ii) drug names and doses of standard therapies that the patient has failed; and

(iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11176F	2	2	0.00	*411.96	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14945N	2	2	0.00	*418.14	[a] Xolair [NV]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

Other anterior pituitary lobe hormones and analogues

PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19071

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) details of the proposed prescription(s); and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack

11177G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	0	0.00	*529.32	Somavert [PF]

PEGVISOMANT

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19071

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

a) details of the proposed prescription(s); and

b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and

d) a recent result of the IGF-1 level and the date of assessment ; and

e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19122

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose.

Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pegvisomant 10 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11179J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,969.64	Somavert [PF]

pegvisomant 15 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11173C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,969.64	Somavert [PF]

pegvisomant 20 mg injection [30 vials] (&) inert substance diluent [30 syringes], 1 pack

11181L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,969.64	Somavert [PF]

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

7025

Acromegaly

Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority Required (STREAMLINED)

4575

Functional carcinoid tumour

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

5777C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*1,699.46	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

5778D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*2,261.74	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

5779E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*2,581.52	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

17635
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Clinical criteria:
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:
- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11513Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*2,581.52	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

OCTREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)
17635
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Clinical criteria:
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:
- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

11893Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,207.32	Sandostatin LAR [NV]

OCTREOTIDE

Authority Required (STREAMLINED)
8165
Acromegaly
Clinical criteria:
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority Required (STREAMLINED)
6390
Functional carcinoid tumour
Clinical criteria:
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

6369

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 50 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9508K	18	11	0.00	*252.00	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.05 [NV]	

octreotide 100 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9509L	18	11	0.00	*504.00	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.1 [NV]	

octreotide 500 microgram/mL injection, 5 x 1 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9510M	18	11	0.00	*1,870.38	[a] Octreotide GH [HQ]	[a] Octreotide (SUN) [RA]
					[a] Sandostatin 0.5 [NV]	

OCTREOTIDE

Authority Required (STREAMLINED)

8161

Acromegaly

Clinical criteria:

- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority Required (STREAMLINED)

5901

Functional carcinoid tumour

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

5906

Vasoactive intestinal peptide secreting tumour (VIPoma)

Clinical criteria:

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10543X	2	5	0.00	*789.16	Sandostatin LAR [NV]

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10533J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,050.62	Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10550G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*1,207.32	Sandostatin LAR [NV]

PASIREOTIDE EMBONATE

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Special Pricing Arrangements apply.

Authority Required

19121

Acromegaly

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; **OR**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be at least 18 years of age.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

a) details of the proposed prescription; and

b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and

c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and

d) a recent result of GH or IGF-1 levels must be provided.

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19069

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

Population criteria:

- Patient must be at least 18 years of age.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR

2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

Caution Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pasireotide (as embonate) 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10886Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*7,410.00	Signifor LAR [RJ]

pasireotide (as embonate) 40 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10883T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*7,410.00	Signifor LAR [RJ]

pasireotide (as embonate) 60 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

10882R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*7,410.00	Signifor LAR [RJ]

CALCIUM HOMEOSTASIS

ANTI-PARATHYROID AGENTS

Other anti-parathyroid agents

CINACALCET

Authority Required

10073

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have failed to respond to conventional therapy, **AND**
- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; **OR**
- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

cinacalcet 30 mg tablet, 28

5621W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*31.32	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 60 mg tablet, 28

5622X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*62.66	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

5623Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*93.98	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

CINACALCET

Authority Required (STREAMLINED)

10067

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a nephrologist.

Clinical criteria:

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

Note "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

cinacalcet 30 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11887P	2	5	0.00	*31.32	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 60 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11886N	2	5	0.00	*62.66	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

cinacalcet 90 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11885M	2	5	0.00	*93.98	[a] Cinacalcet Viatris [AL]	[a] Pharmacor Cinacalcet [CR]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIBACTERIALS FOR SYSTEMIC USE

MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS

Macrolides

AZITHROMYCIN

Authority Required (STREAMLINED)

6356

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

azithromycin 600 mg tablet, 8

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5616N NP	2	5	0.00	*110.76	Zithromax [PF]

ANTIMYCOBACTERIALS

DRUGS FOR TREATMENT OF TUBERCULOSIS

Antibiotics

RIFABUTIN

Authority Required (STREAMLINED)

6350

Mycobacterium avium complex infection

Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

Authority Required (STREAMLINED)

6356

Mycobacterium avium complex infection

Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**

- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

rifabutin 150 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9541E NP	4	5	0.00	*525.84	Mycobutin [PF]

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority Required (STREAMLINED)

15800

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority Required (STREAMLINED)

15814

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

ganciclovir 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5749N	2	1	0.00	*232.18	[a] Cymevene [PB]	[a] GANCICLOVIR SXP [XC]

VALACICLOVIR

Authority Required (STREAMLINED)

5975

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

Clinical criteria:

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

valaciclovir 500 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9568N	5	2	0.00	*200.00	[a] APX-Valaciclovir [TY]	[a] Valaciclovir RBX [RA]
			[B]13.50	*213.50	[a] Valtrex [RW]	

VALGANCICLOVIR

Authority Required (STREAMLINED)

15800

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

Authority Required (STREAMLINED)

15814

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9655E	11	5	0.00	*4,346.10	Valcyte [PB]

valganciclovir 450 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9569P	2	5	0.00	*476.22	[a] Valganciclovir Sandoz [SZ]	[a] Valganciclovir Viatris [AL]

Antivirals for treatment of HCV infections

GLECAPREVIR + PIBRENTASVIR

Authority Required

7593

Chronic hepatitis C infection

Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11332K NP	1	1	0.00	16,846.67	Maviret [VE]

GLECAPREVIR + PIBRENTASVIR

Authority Required
10268
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11333L NP	1	3	0.00	16,846.67	Maviret [VE]

GLECAPREVIR + PIBRENTASVIR

Authority Required
7615
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11345D NP	1	2	0.00	16,846.67	Maviret [VE]

SOFOSBUVIR + VELPATASVIR

Authority Required
5969
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11145N NP	1	2	0.00	11,875.00	Epclusa [GI]

SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required
10248
Chronic hepatitis C infection
Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11665Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
NP	1	2	0.00	11,875.00	Vosevi [GI]

Other antivirals

MARIBAVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)
16735
Cytomegalovirus infection and disease
Clinical criteria:

- Patient must have received a hematopoietic stem-cell transplant; **OR**
- Patient must have received a solid-organ transplant, **AND**
- Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; **OR**
- Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, **AND**
- The treatment must be used as monotherapy for this condition under this restriction, **AND**
- Patient must not have previously demonstrated resistance to this drug, **AND**
- Patient must not have cytomegalovirus disease that involves the central nervous system, **AND**
- Patient must not have cytomegalovirus retinitis.

For the purpose of administering this restriction:
(i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level.
(ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet.
(iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.

maribavir 200 mg tablet, 28

14856X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	1	0.00	*28,200.00	Livtencity [TK]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ANTIMETABOLITES

Pyrimidine analogues

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Authority Required
19124
Chronic Myelomonocytic Leukaemia
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and

(b) full blood examination report

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

azacitidine 100 mg injection, 1 vial

9597D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Authority Required (STREAMLINED)

12986

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

azacitidine 100 mg injection, 1 vial

13044M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	5	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13015

Chronic Myelomonocytic Leukaemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9598E	14	5	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12439

Acute Myeloid Leukaemia

Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

azacitidine 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12771E	14	2	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13011

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

Up to 6 cycles will be authorised.

azacitidine 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13028Q	14	5	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
					[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
					[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13010

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
(b) full blood examination report.

azacitidine 100 mg injection, 1 vial

13036D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

AZACITIDINE

Caution This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

12983

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); **OR**
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS).

Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:

a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR

b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR

c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR

f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR

b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR

d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

The following information must be provided by the prescriber at the time of application:

(a) The patient's International Prognostic Scoring System (IPSS) score

The following reports must be documented in the patient's medical records:

(a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and

(b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

azacitidine 100 mg injection, 1 vial

13042K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14	2	0.00	*204.82	[a] Azacitidine Accord [OC]	[a] Azacitidine Dr.Reddy's [RI]
				[a] Azacitidine Juno [JO]	[a] Azacitidine MSN [JU]
				[a] Azacitidine SXP [XN]	

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority Required (STREAMLINED)

6234

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

Authority Required (STREAMLINED)

6274

Kaposi sarcoma

Clinical criteria:

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5705G NP	4	5	0.00	*553.68	[a] Caelyx [BX]	[a] Liposomal Doxorubicin SUN [RA]

PROTEIN KINASE INHIBITORS

Janus-associated kinase (JAK) inhibitors

RUXOLITINIB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

13907

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ruxolitinib 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13243B	1	0	0.00	2,256.25	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13232K	1	0	0.00	4,512.50	Jakavi [NV]

RUXOLITINIB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

19147

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

Treatment criteria:

- Must be treated by a specialist medical practitioner; **OR**
- Must be treated by an authorised prescriber type (non-specialist medical practitioner, nurse practitioner) who is both: (i) continuing existing therapy with this medicine (i.e. not initiating treatment), (ii) has agreement from the treating specialist medical practitioner.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ruxolitinib 5 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13238R NP	1	5	0.00	2,256.25	Jakavi [NV]

ruxolitinib 10 mg tablet, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13245D NP	1	5	0.00	4,512.50	Jakavi [NV]

Other protein kinase inhibitors

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required

19073

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and

(b) confirmation that the patient does not have progressive disease; and

(c) details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and

(d) details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

midostaurin 25 mg capsule, 112

11552B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	18,422.74	Rydapt [NV]

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

11699

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;

- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 112

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11505M	1	2	0.00	18,422.74	Rydapt [NV]

MIDOSTAURIN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13001

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition; **OR**
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

midostaurin 25 mg capsule, 56

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11553C	1	2	0.00	9,211.37	Rydapt [NV]

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD20 (Clusters of Differentiation 20) inhibitors

OBINUTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

19188

Lupus nephritis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must not have demonstrated evidence of clinically significant worsening of the condition, confirmed by either: (i) an increase in urinary protein-to-creatinine ratio (UPCR); or (ii) a reduction in estimated glomerular filtration rate (eGFR) from baseline values, due to persisting active class III or IV lupus nephritis, based on 2 measurements taken 3 months apart, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The values for UPCR and eGFR, taken 3 months apart, used to determine the patient's response to treatment, must be documented in the patient's medical records.

obinutuzumab 1 g/40 mL injection, 40 mL vial

15526E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,299.24	Gazyva [RO]

OBINUTUZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

19168

Lupus nephritis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed diagnosis of active class III or IV lupus nephritis with or without class V disease, confirmed by renal biopsy, **AND**
- Patient must not have severe renal impairment, demonstrated by an estimated glomerular filtration rate (eGFR) less than 30 mL/min/1.73 m^2, **AND**
- Patient must have/have had a urinary protein-to-creatinine ratio (UPCR) of at least 113 mg/mmol (equivalent to 1g/g) prior to initiation of treatment with this drug, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The baseline values of the eGFR and UCPR must be documented in the patient's medical records, as it will inform the basis for determining if worsening of the condition has occurred.

Authority Required

19169

Lupus nephritis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must not have sustained clinically significant, worsening from baseline values of either: (i) urinary protein-to-creatinine ratio (UPCR); and/or (ii) estimated glomerular filtration rate (eGFR), as determined by the treating physician, **AND**
- The treatment must be administered with mycophenolate and corticosteroids unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- The treatment must not be used in combination with anifrolumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

The current values for UPCR and eGFR, used to determine the patient's response to treatment, must be documented in the patient's medical records.

obinutuzumab 1 g/40 mL injection, 40 mL vial

15510H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	1	0.00	4,299.24	Gazyva [RO]

RITUXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 500 mg/50 mL injection, 50 mL vial

13101M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	1	0.00	*432.36	[a] Riximyo [SZ]	[a] Ruxience [PF]
				[a] Truxima [EW]	

RITUXIMAB

Note Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

rituximab 100 mg/10 mL injection, 2 x 10 mL vials

13082M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	0	0.00	*259.44	[a] Riximyo [SZ]	[a] Truxima [EW]

rituximab 100 mg/10 mL injection, 10 mL vial

13088W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	0	0.00	*259.44	[a] Ruxience [PF]

OTHER ANTINEOPLASTIC AGENTS

Other antineoplastic agents

EFLORNITHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16841

High-risk neuroblastoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have high-risk neuroblastoma according to a validated risk classification system, **AND**
- Patient must be in remission, with at least a partial response, at the end of multiagent, multimodality therapy for high-risk neuroblastoma, **AND**
- The treatment must be initiated after completing previous therapy, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist.

Prior to initiating treatment with this drug, a complete blood count, liver function tests and baseline hearing assessments should be performed and documented in the patient's medical records.

At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information.

The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription).

Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 m^2 to less than 0.5 m^2;
Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 m^2 to less than 0.75 m^2;
Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 m^2 to 1.5 m^2;
Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.
Authority applications for initial treatment must be made in writing and must include:
(a) details of the proposed prescription; and
(b) a completed PBS authority application form, relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
(i) details of prior multiagent, multimodality therapy for high-risk neuroblastoma [date of commencement and duration of therapy]; and
(ii) the patient's BSA measurement.

eflornithine 192 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14880E	3	2	0.00	*34,622.40	Ifinwil [NE]

EFLORNITHINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required
17753
High-risk neuroblastoma
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease recurrence while receiving treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 27 cycles (based on 4 weeks per cycle) from the first dose of this drug, regardless of whether it was PBS/non-PBS-subsidised.

Treatment criteria:

- Must be treated in a hospital/cancer centre by either a: (i) paediatric oncologist, (ii) haematologist; **OR**
- Must be treated by a medical practitioner under the direct supervision of either a: (i) paediatric oncologist, (ii) haematologist.

At the time of the authority application, the prescriber should request an appropriate quantity and number of repeats based on the patient's Body Surface Area (BSA), according to the dosing schedule in the TGA approved Product Information.
The following maximum quantity units and repeats may be authorised under this restriction (providing 3 months of therapy for each prescription).
Up to a maximum quantity of 100 units and 1 repeat for a BSA 0.25 m^2 to less than 0.5 m^2;
Up to a maximum quantity of 200 units and 1 repeat for a BSA 0.5 m^2 to less than 0.75 m^2;
Up to a maximum quantity of 200 units and 2 repeats for a BSA 0.75 m^2 to 1.5 m^2;
Up to a maximum quantity of 300 units and 2 repeats for a BSA greater than 1.5 m^2.

eflornithine 192 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14894X	3	2	0.00	*34,622.40	Ifinwil [NE]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required
14021
Relapsed and/or refractory multiple myeloma
Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week
Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**

- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14045

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 16

13085Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	9,360.00	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

14024

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14023

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; **OR**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 20

13086R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	11,700.00	Xpovio [TG]

SELINEXOR

Caution This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

14039

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

Authority Required

14031

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

selinexor 20 mg tablet, 32

13104Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	18,720.00	Xpovio [TG]

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Colony stimulating factors

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**

- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2758E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	0.00	*234.92	[a] Zarzio [SZ]

filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5742F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*234.92	[a] Nivestim [PF]

FILGRASTIM

Note Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**

- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes

2783L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	11	0.00	*376.60	[a] Zarzio [SZ]

filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes

5744H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*376.60	[a] Nivestim [PF]

FILGRASTIM

Authority Required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

6653

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

Authority Required (STREAMLINED)

6654

Mobilisation of peripheral blood progenitor cells

Clinical criteria:

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

Authority Required (STREAMLINED)

6679

Assisting bone marrow transplantation

Clinical criteria:

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

Authority Required (STREAMLINED)

6655

Assisting autologous peripheral blood progenitor cell transplantation

Clinical criteria:

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

Authority Required (STREAMLINED)

6680

Severe congenital neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

Authority Required (STREAMLINED)

6621

Severe chronic neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; **OR**
- Patient must have neutrophil dysfunction, **AND**

- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

Authority Required (STREAMLINED)

6640

Chronic cyclical neutropenia

Clinical criteria:

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; **OR**
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes

5829T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	11	0.00	*247.68	Nivestim [PF]

LIPEGFILGRASTIM

Authority Required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

10936N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	11	0.00	1,116.25	Lonquex [TB]

PEGFILGRASTIM

Authority Required (STREAMLINED)

7822

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; **OR**
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

Authority Required (STREAMLINED)

7843

Chemotherapy-induced neutropenia

Clinical criteria:

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; **OR**
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe

9514R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	11	0.00	77.52	[a] Pelgraz [OC]	[a] Ziextenzo [SZ]

Interferons

INTERFERON GAMMA-1B

Authority Required (STREAMLINED)

6222

Chronic granulomatous disease

Clinical criteria:

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5769P	2	11	0.00	*1,719.56	Imukin [LM]

PEGINTERFERON ALFA-2A

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Pharmaceutical benefits that have the brand Pegasys (Ireland) can be substituted for Pegasys in the case of a shortage.

Authority Required (STREAMLINED)

17022

Chronic hepatitis C infection

Treatment criteria:

- Must be treated in an accredited treatment centre.

Population criteria:

- Patient must be at least 18 years of age
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

Clinical criteria:

- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

Caution Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Note Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

(a) a nurse educator/counsellor for patients; and (b) 24-hour access by patients to medical advice; and (c) an established liver clinic.

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
9515T NP	2	5	0.00	*1,657.28	[a]	Pegasys [XO]

peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
15025T NP	2	5	0.00	*2,359.14	[a]	Pegasys (Ireland) [XO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
9516W NP	2	5	0.00	*1,919.26	[a]	Pegasys [XO]

peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
14993D NP	2	5	0.00	*2,464.92	[a]	Pegasys (Ireland) [XO]

Other immunostimulants

PLERIXAFOR

Authority Required (STREAMLINED)

4549

Mobilisation of haematopoietic stem cells

Clinical criteria:

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; **OR**
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; **OR**
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; **OR**

- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

plerixafor 24 mg/1.2 mL injection, 1.2 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
10083Q	1	1	0.00	1,129.54	[a] Plerixafor ARX [XT]	[a] PLERIXAFOR EUGIA [YG]

IMMUNOSUPPRESSANTS

IMMUNOSUPPRESSANTS

Selective immunosuppressants

ABATACEPT

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14604

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number

of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

abatacept 250 mg injection, 1 vial

13725J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	5	0.00	*787.20	Orencia [BQ]

ABATACEPT

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the

next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18169

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18272

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18274

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14488

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18273

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

abatacept 250 mg injection, 1 vial

5605B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	262.40	Orencia [BQ]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5554

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

mycophenolate mofetil 500 mg tablet, 50

9502D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
6	5	0.00	*115.08	[a] ARX-MYCOPHENOLATE [XT]	[a] Ceptolate [AF]
				[a] Mycophenolate GH [GQ]	[a] Mycophenolate Sandoz [SZ]
				[a] Pharmacor Mycophenolate 500 [CR]	

mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL

9500B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*372.20	[a] CellCept [RO]	[a] Pharmacor Mycophenolate [CR]

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5653

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5600

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

mycophenolate mofetil 250 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9501C	6	5	0.00	*115.20	[a] APO-Mycophenolate [TX]	[a] Mycophenolate Sandoz [SZ]
					[a] Pharmacor Mycophenolate 250 [CR]	

MYCOPHENOLATE

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

4084

Prophylaxis of renal allograft rejection

Treatment Phase: Management

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

Authority Required (STREAMLINED)

4095

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

Clinical criteria:

- The condition must be proven by biopsy.

Treatment criteria:

- Must be treated by a nephrologist or in consultation with a nephrologist.

The name of the consulting nephrologist must be included in the patient medical records.

Caution Careful monitoring of patients is mandatory.

Note Management includes initiation, stabilisation and review of therapy as required.

mycophenolate 180 mg enteric tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9503E	2	5	0.00	*171.58	[a] Mycophenolic Acid ARX [XT]	[a] Myfortic [NV]

mycophenolate 360 mg enteric tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
9504F	2	5	0.00	*261.14	[a] Mycophenolic Acid ARX [XT]	[a] MYCOTEX [CR]
					[a] Myfortic [NV]	

Tumor necrosis factor alpha (TNF-alpha) inhibitors

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

12406Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	567.42	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12435L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	0	0.00	*545.68	[a] Amgevita [XT]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

15138R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

15139T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15177T	1	5	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
					[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
15141X	1	5	0.00	444.17	[a] Amgevita [XT]	[a] Hadlima [RF]
					[a] Hyrimoz [SZ]	

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17734

Severe active juvenile idiopathic arthritis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 January 2026, **AND**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have, prior to initiating treatment with this drug for this condition, demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**

- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age, prior to commencement of this drug for this condition.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

15156Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	567.42	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

15143B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*545.68	[a] Amgevita [XT]

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

13228F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

12348X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Amgevita [XT]	[a] Hadlima [RF]
				[a] Hyrimoz [SZ]	

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

13212J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

12355G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	444.17	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ADALIMUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

Note Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes

13293P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	567.42	[a] Humira [VE]

adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe

12417M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*545.68	[a] Amgevita [XT]

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes

12431G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes

9662M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	444.17	[a] Amgevita [XT]	[a] Hadlima [RF]
				[a] Hyrimoz [SZ]	

ADALIMUMAB

Note Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17719

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17733

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17717

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices

12444Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	444.17	[a] Hadlima [RF]	[a] Humira [VE]
				[a] Hyrimoz [SZ]	[a] Yuflyma [EW]

adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices

9663N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	444.17	[a] Abrilada [PF]	[a] Amgevita [XT]
				[a] Hadlima [RF]	[a] Hyrimoz [SZ]

ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17724

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17725

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17706

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 50 mg/mL injection, 4 x 1 mL syringes

5733R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	743.60	[a] Enbrel [PF]	[a] Erelzi [SZ]

5733R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Nepexto [GQ]	

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

5735W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	743.60	[a] Enbrel [PF]	[a] Erelzi [SZ]
					[a] Nepexto [GQ]	

ETANERCEPT

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

13294Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	5	0.00	*743.62	Enbrel [PF]

ETANERCEPT

Caution Etanercept 50 mg/mL 1ml pen devices and prefilled syringes are intended for use in children and adolescents weighting 62.5kg or more.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

etanercept 50 mg/mL injection, 4 x 1 mL syringes

13308K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	743.60	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

etanercept 50 mg/mL injection, 4 x 1 mL pen devices

13319B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	743.60	[a] Enbrel [PF]	[a] Erelzi [SZ]
				[a] Nepexto [GQ]	

ETANERCEPT

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

17724

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii)

oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**

- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17725

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17706

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack

5734T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	371.81	Enbrel [PF]

INFLIXIMAB

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Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

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Authority Required

18994

Moderate to severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must not have achieved an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy with a thiopurine at a clinically optimised dose, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; **OR**
- Patient must have a documented contraindication to each of prednisolone (or equivalent), a thiopurine, and methotrexate; **OR**
- Patient must have features of high-risk or complicated Crohn disease defined as those with any of the following: (i) perianal disease, (ii) stricturing or penetrating behaviour, (iii) severe delayed growth (growth velocity at least 2 standard deviations below the mean for age and sex, or a drop of at least 1 major centile band), **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30; **OR**
- Patient must have extensive intestinal inflammation of the small intestine as evidenced by radiological imaging, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) current PCDAI score and the date of assessment; or

(c) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18995

Moderate to severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must not have previously received this drug for this condition in this treatment cycle; **OR**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response; **OR**
- Patient must have: (i) received this drug in this treatment cycle, (ii) not demonstrated/maintained an adequate response to this drug once in this treatment cycle, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the PCDAI score and the date of assessment; or

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' clinical and treatment criteria when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18992

Moderate to severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease while off treatment with targeted therapy, **AND**
- Patient must not receive more than 12-14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current PCDAI score and the date of assessment; or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with extensive small intestine disease.

For patients assessed as having extensive intestinal inflammation of the small intestines, such evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight with 3 repeats will be authorised.

If fewer than 3 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Where a response assessment is not conducted, the patient will be deemed to have not responded to treatment with this drug. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18993

Moderate to severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1, 2 or 3), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

infliximab 100 mg injection, 1 vial

5755X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

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Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required

19107

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19108

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

19152

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19176

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, or Continuing treatment), **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1 or 2 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

9654D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased quantities/repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Authority Required

18774

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

18866

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Authority Required

18849

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18775

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic

imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

A maximum quantity and number of repeats to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered every 8 weeks will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

18776

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under the Initial 1, 2 or 3 restrictions to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient treatment with this drug for this condition under the Continuing restriction to complete 24 weeks of treatment (8-weekly infusion regimen), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

infliximab 100 mg injection, 1 vial

5754W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18436

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18468

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18469

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

18439

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

Clinical criteria:

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website (www.servicesaustralia.gov.au).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18287

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18352

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets, and the face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

11158

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18470

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18437

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

8296

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate).

Treatment criteria:

- Must be treated by a dermatologist.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5758C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required (STREAMLINED)

4524

Acute severe ulcerative colitis

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

Clinical criteria:

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; **OR**
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

Population criteria:

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

Note No increase in the maximum number of repeats may be authorised.

infliximab 100 mg injection, 1 vial

10067W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

18158

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**

- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11482H	1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18164

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

11497D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority Required

18391

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18431

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) details of the proposed prescription(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

infliximab 100 mg injection, 1 vial

11606W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for 'severe Crohn disease' and infliximab for 'moderate to severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time or Initial 3 type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if 3 trials of a targeted therapy do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies. A paediatric patient cannot trial and not demonstrate an adequate response, or cease to respond to, the same PBS-subsidised targeted therapy more than twice.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment Phases:

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks for infliximab.

Initial 1 - use when the patient has never received a PBS-subsidised targeted therapy for these indications. Inadequate response to conventional therapy must be demonstrated where required.

Initial 2 - use when:

- an alternative targeted therapy is being prescribed for these indications; or
- the patient has previously been treated with this targeted therapy; or
- treatment is resuming after a break of less than 12 months

Patients applying through this treatment phase do not have to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Inadequate response to conventional therapy does not need to be redemonstrated.

Initial 3 - use when treatment is resuming after a break in PBS-subsidised treatment of at least 12 months. Patients applying through this treatment phase must requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease). Re-trial of conventional therapies is not required.

Continuing treatment - use when a patient has demonstrated an adequate response to the preceding supply. Patients are eligible for up to 24 weeks of treatment per continuing prescription. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Baseline measurements to determine response - a response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements provided in the first authority application for a targeted therapy. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

Recency of assessments:

Where possible, all related assessment documentation (including the Paediatric Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Consistent with clinical guidelines, therapeutic drug monitoring is recommended during drug escalation/de-escalation to target trough medication levels

Authority Required (STREAMLINED)

19042

Moderate to severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have both: (i) a total PCDAI score of 30 points or less, and (ii) a reduction in PCDAI score by at least 15 points from baseline value; **OR**
- Patient must have an adequate response to this drug defined as an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Population criteria:

- Patient must be aged 6 to 17 years inclusive.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition under this treatment phase. Patients may re-trial treatment with this drug under the 'Initial 2' treatment phase if eligible. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An increase in the maximum quantity to allow for dosing of up to 10 mg per kg body weight will be authorised.

An increase in maximum repeats to 5 may be requested.

infliximab 100 mg injection, 1 vial

11449N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required

12059

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

11459D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]

11459D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14504

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

infliximab 100 mg injection, 1 vial

11490R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	2	0.00	*558.48	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note **TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

9188

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note No increase in the maximum number of repeats may be authorised.

infliximab 100 mg injection, 1 vial

11514B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11514B					[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply

treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14638

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

infliximab 100 mg injection, 1 vial

13734W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
3	2	0.00	*558.48	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required (STREAMLINED)

18819

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no

greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11400B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required (STREAMLINED)

12042

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; **OR**
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

infliximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11461F	5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required (STREAMLINED)

14683

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required (STREAMLINED)

14701

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11486M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	3	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of

disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

Authority Required (STREAMLINED)

8844

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required (STREAMLINED)

8940

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Treatment criteria:

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

infliximab 100 mg injection, 1 vial

11605T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Authority applications for increased quantities may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required (STREAMLINED)

19207

Complex refractory Fistulising Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

An adequate response is defined as:

(a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or

(b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

If a patient does not demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum quantity to provide for each continuing course of this drug consisting of 3 doses at 5 mg per kg body weight per dose will be authorised.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

infliximab 100 mg injection, 1 vial

11423F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5	2	0.00	*930.80	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

14718

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and

(iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

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Authority Required

14707

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

14667

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

infliximab 100 mg injection, 1 vial

13765L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

14502

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14623

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14544

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of result;

(b) the most recent biological agent and the date of the last continuing prescription.

(c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14548

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

infliximab 100 mg injection, 1 vial

13723G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remsima [EW]	[a] Renflexis [OQ]

INFLIXIMAB

Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18502

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by

achieving and maintaining a partial Mayo clinic scoreless than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18196

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; **OR**
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; **OR**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18355

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); **OR**
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; **OR**
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

Population criteria:

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9754

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; **OR**
- Must be treated by a paediatrician; **OR**
- Must be treated by a specialist paediatric gastroenterologist.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

10196P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
					[a] Remicade [JC]	[a] Remsima [EW]
					[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

Authority Required

18340

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

(a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and

(b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a completed Exercise Program Self Certification Form included in the supporting information form; and

(iv) baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at www.servicesaustralia.gov.au

Note For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at www.servicesaustralia.gov.au

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18162

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18263

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; **OR**
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18462

Ankylosing spondylitis

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

(a) an ESR measurement no greater than 25 mm per hour; or

(b) a CRP measurement no greater than 10 mg per L; or

(c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9559

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**

- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14705

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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infliximab 100 mg injection, 1 vial

5753T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18191

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; **OR**
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**

- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website (www.humanservices.gov.au)

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18192

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18194

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9111

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18441

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9068

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

infliximab 100 mg injection, 1 vial

5756Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

INFLIXIMAB

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

18165

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18345

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18267

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14548

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18343

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

infliximab 100 mg injection, 1 vial

5757B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	186.16	[a] Inflectra [PF]	[a] Ixifi [FZ]
				[a] Remicade [JC]	[a] Remsima [EW]
				[a] Renflexis [OQ]	

Interleukin inhibitors

ANAKINRA

Authority Required (STREAMLINED)

5450

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

Treatment criteria:

- Must be treated by a rheumatologist or in consultation with a rheumatologist; **OR**
- Must be treated by a clinical immunologist or in consultation with a clinical immunologist.

A diagnosis of CAPS must be documented in the patient's medical records.

Note This drug is not PBS-subsidised for conditions other than CAPS.

anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes

10264F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,146.64	Kineret [ZO]

SILTUXIMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

12585

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; **OR**

- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

Note The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.

Details of these criteria are presented in Table 2 of the following literature article:

Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. *Blood* 2017; 129(12): 1646-1657.

Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.

Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

Authority Required

12594

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

siltuximab 100 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12916T	2	4	0.00	*1,558.56	Sylvant [RJ]

siltuximab 400 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12922D	2	4	0.00	*6,234.20	Sylvant [RJ]

TOCILIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

Authority Required

18174

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 80 mg/4 mL injection, 4 mL vial

12775J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

12791F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12763R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and

2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

14093

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 200 mg/10 mL injection, 10 mL vial

13330N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*401.42	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13299Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*798.78	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

17707

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13324G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*161.94	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13305G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13339C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required (STREAMLINED)

14621

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; **OR**
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13690M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*161.94	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

13684F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

13715W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority Required

18348

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

Authority Required

18280

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilzumab after resolution of the critical shortage of tocilizumab)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

tocilizumab 80 mg/4 mL injection, 4 mL vial

12794J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

12796L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

12802T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing

treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required (STREAMLINED)

14093

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

tocilizumab 80 mg/4 mL injection, 4 mL vial

13304F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*323.88	Actemra [RO]

TOCILIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

1) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy; and
2) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application

Initial treatment

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

Continuing treatment

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

Baseline measurements to determine response

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

Recommencement of treatment after a 12-month break in PBS-subsidised therapy

Apply under the 'Initial 3' treatment listing.

Withdrawal of treatment after sustained remission

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

14148

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; **OR**
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

(a) an active joint count of at least 2 active joints; and

(b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or

(c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and

(b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Authority Required

14091

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retrial or recommencement of treatment after a break of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retrial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

14085

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); **OR**
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Population criteria:

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

10570

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

tocilizumab 80 mg/4 mL injection, 4 mL vial

1476Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

1481Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

1482B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

Authority Required

17712

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; **OR**
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 10 active (swollen and tender) joints; or

(b) an active joint count of at least 2, affecting the following joints: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; or

(e) development/worsening of erosive disease due to active arthritis.

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

Authority Required

17714

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 10 active joints; or

(b) a reduction in the number of the following active joints, from at least 2, by at least 50%: elbow, wrist, knee, ankle, shoulder, and hip; or

(c) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting the cervical spine or temporomandibular joint; or

(d) at least a 50% reduction from baseline on the frequency of oral or intra-articular corticosteroids use to control flares of disease associated with active arthritis; or

(e) an improvement from baseline by at least 50% in the signs and symptoms attributable to active arthritis affecting joint(s) with erosive disease.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Authority Required

17729

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 10 active (swollen and tender) joints; (b) at least 2 active major joints; (c) active arthritis affecting the cervical spine or temporomandibular joint; (d) at least 2 separate episodes of oral or intra-articular corticosteroids use within 12 months to control flares of disease; (e) development/worsening of erosive disease due to active arthritis, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active major joints are defined as: elbow, wrist, knee, ankle, shoulder, and hip.

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 10 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active major joints, the response must be demonstrated on the total number of active major joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Authority Required

12120

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

Treatment criteria:

- Must be treated by a paediatric rheumatologist; **OR**
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

tocilizumab 80 mg/4 mL injection, 4 mL vial

10077J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10056G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10064Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline

measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

Authority Required

18275

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18172

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have received PBS-subsided treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18276

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14488

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18346

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

14507

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

9657G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

9658H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

9659J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	399.39	Actemra [RO]

TOCILIZUMAB

Note TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

Authority Required

18180

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; **OR**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; **OR**
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note The Department of Human Services website (www.humanservices.gov.au) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose; (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial; (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18177

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18282

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

Treatment criteria:

- Must be treated by a rheumatologist; **OR**

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; **OR**
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; **OR**
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

9386

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority Required

18279

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Population criteria:

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

9380

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing Treatment - balance of supply

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

Note Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

tocilizumab 80 mg/4 mL injection, 4 mL vial

10081N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	80.97	Actemra [RO]

tocilizumab 200 mg/10 mL injection, 10 mL vial

10058J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	200.71	Actemra [RO]

tocilizumab 400 mg/20 mL injection, 20 mL vial

10072D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	399.39	Actemra [RO]

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of 'complex refractory fistulising Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under the Initial 1 or Initial 2 who are accessing PBS-subsidised treatment for the first time. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and do not provide an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy, through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication or if the patient has had a break in targeted therapy of at least 12-months. Patients who have had a break in treatment of at least 12-months must requalify for treatment with respect to the indices of disease severity.

Initial 2 - use when:

- an alternative targeted therapy is prescribed for this indication, or
- the patient has previously been treated with this targeted therapy, or
- treatment is resuming after a break of less than 12-months.

Baseline disease activity does not need to be re demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply. A response to treatment is determined by comparison of current disease activity measurements relative to the baseline measurements. Prescribers may provide new baseline measurements any time that an initial treatment authority application is made within a treatment cycle and eligibility will be assessed against the revised baseline measurements. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be determined.

Recency of assessments:

Where possible, all related assessment documentation should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note For the purposes of this restriction, the fistula symptom grading total score can be calculated using the following:

(i) Discharge

- 0 - no discharge
- 1 - minimal mucous discharge
- 2 - moderate mucous discharge or purulent discharge
- 3 - substantial discharge
- 4 - gross faecal soiling

(ii) Pain

- 0 - no pain
- 1 - mild discomfort
- 2 - moderate discomfort
- 3 - marked discomfort
- 4 - severe pain

(iii) Degree of induration

- 0 - no induration
- 1 - minimal induration
- 2 - moderate induration
- 3 - substantial induration
- 4 - gross fluctuance/abscess

Authority Required

19171

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

The number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition must be provided by the prescriber at the time of application and documented in the patient's medical records.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19172

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) current number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment of the patient's condition; and

(b) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The application must also provide details of the baseline scores of the prior eligibility requirements, including the number of externally draining complex fistulae, fistula symptom grading scores (discharge/pain/induration) and the date of assessment.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 1 treatment restriction.

Authority Required

19149

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial restriction (Initial 1 or Initial 2), **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

ustekinumab 130 mg/26 mL injection, 26 mL vial

13781H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,242.92	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a

cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Authority Required

18825

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18856

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18785

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Where fewer than 2 doses are requested at the time of the application, authority approvals for sufficient treatment based on the patient's weight to complete dosing at weeks 0 and 8 may be requested through the Balance of supply restriction.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

ustekinumab 130 mg/26 mL injection, 26 mL vial

11182M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,242.92	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

USTEKINUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Authority Required

16958

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy (dosage, date of commencement and duration of therapy).

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the toxicities, including severity, which will be accepted where one is claimed.

Authority Required

16939

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Authority Required

16866

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

ustekinumab 130 mg/26 mL injection, 26 mL vial

13272M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	0	0.00	*2,242.92	[a] Stelara [JC]	[a] Steqeyma [EW]
				[a] Wezlana [TN]	

Calcineurin inhibitors

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6628

Management of transplant rejection

Clinical criteria:

- The treatment must be used by organ or tissue transplant recipients.

Caution Careful monitoring of patients is mandatory.

ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules

5631J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	54.10	Sandimmun [NV]

CICLOSPORIN

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6643

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6660

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Treatment criteria:

- Must be treated by a dermatologist; **OR**
- Must be treated by a clinical immunologist.

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

15360

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must be ineffective to other systemic therapies; **OR**
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

Treatment criteria:

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; **OR**
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6631

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must have failed prior treatment with steroids and cytostatic drugs; **OR**
- Patient must be intolerant to treatment with steroids and cytostatic drugs; **OR**
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

Treatment criteria:

- Must be treated by a nephrologist.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

6638

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); **OR**
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

Treatment criteria:

- Must be treated by a rheumatologist; **OR**
- Must be treated by a clinical immunologist.

Caution Careful monitoring of patients is mandatory.

ciclosporin 10 mg capsule, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5632K	2	5	0.00	*74.40	Neoral 10 [NV]

ciclosporin 25 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5634M	4	5	0.00	*88.16	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 25 [NV]	

ciclosporin 50 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5635N	4	5	0.00	*183.48	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 50 [NV]	

ciclosporin 100 mg capsule, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5636P	4	5	0.00	*373.80	[a] APO-Ciclosporin [TX]	[a] CICLOSPORIN-WGR [WG]
					[a] Neoral 100 [NV]	

ciclosporin 100 mg/mL oral liquid, 50 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5633L	4	5	0.00	*1,263.16	Neoral [NV]

TACROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5569

Management of rejection in patients following organ or tissue transplantation

Clinical criteria:

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

Caution Careful monitoring of patients is mandatory.

tacrolimus 500 microgram capsule, 100

9558C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*102.96	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 0.5 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 500 microgram modified release capsule, 30

9664P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*75.04	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 750 microgram capsule, 100

10859M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*164.14	Tacrolimus Sandoz [SZ]

tacrolimus 1 mg capsule, 100

9560E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*205.92	[a] Pacrolim [AF]	[a] Pharmacor Tacrolimus 1 [CR]
					[a] Prograf [LL]	[a] Tacrograf [RW]
					[a] Tacrolimus Sandoz [SZ]	

tacrolimus 1 mg modified release capsule, 60

9665Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*123.56	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 2 mg capsule, 100

10860N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*469.30	Tacrolimus Sandoz [SZ]

tacrolimus 3 mg modified release capsule, 50

11907Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	0.00	*658.20	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

tacrolimus 5 mg capsule, 50

9561F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*514.56	[a] Pharmacor Tacrolimus 5 [CR]	[a] Prograf [LL]
					[a] Tacrograf [RW]	[a] Tacrolimus Sandoz [SZ]

tacrolimus 5 mg modified release capsule, 30

9666R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*750.44	[a] ADVAGRAF XL [LQ]	[a] Tacrolimus XR Sandoz [SZ]

Monoclonal antibodies

ALEMTUZUMAB

Authority Required (STREAMLINED)

7714

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10228H	5	0	0.00	*51,415.45	Lemtrada [GZ]

ALEMTUZUMAB

Authority Required (STREAMLINED)

6847

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

Note Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

Note Special Pricing Arrangements apply.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10232M	3	0	0.00	*30,849.27	Lemtrada [GZ]

ANIFROLUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19216

Systemic lupus erythematosus

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019, **AND**
- Patient must have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points, **AND**
- Patient must be currently receiving hydroxychloroquine, with treatment received for at least 12 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving immunosuppressant medication, with treatment received for at least 12 weeks, with either: (i) minimum dose of methotrexate 20 mg per week, (ii) azathioprine 100 mg per day, (iii) mycophenolate 1,000 mg per day unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving prednisolone or equivalent of at least 7.5 mg per day, with treatment received for at least 4 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus, **AND**
- The treatment must not be used in combination with obinutuzumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.

Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.

If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg

per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

(a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;

(b) details (date and score) of the completed SLEDAI-2K score sheet;

(c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);

(d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

19096

Systemic lupus erythematosus

Treatment Phase: Continuing or recommencement of treatment (within 12 months of a treatment break)

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must be responding to treatment if they have received less than 12 months of treatment with this drug for this condition; **OR**
- Patient must have attained a Lupus Low Disease Activity State (LLDAS) and maintained this state while on treatment, **AND**
- The treatment must not be used in combination with obinutuzumab.

Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

Lupus Low Disease Activity State (LLDAS) is defined as:

(a) Total SLEDAI-2K of not greater than 4, with no major activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever); and

(b) No new features of lupus disease activity compared with the previous assessment, and

(c) Physician Global Assessment (PGA) of not greater than 1, and

(d) Current prednisolone (or equivalent) dose of not greater than 7.5 mg daily, and

(e) Well tolerated standard maintenance doses of anti-malarial and immunosuppressive drugs are allowed.

Where retreatment with anifrolumab after a break in PBS-subsidised treatment with anifrolumab is being sought, the date of cessation of the previous treatment course with anifrolumab must be included in the application. Recommencement of treatment with anifrolumab for severe SLE is within 12 months from the date that treatment was ceased.

Note SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

Note PGA can be accessed via Petri 2005 N Engl J Med 353: 2550-8.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

anifrolumab 300 mg/2 mL injection, 2 mL vial

14195D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,448.00	Saphnelo [AP]

NATALIZUMAB

Caution Progressive multifocal leukoencephalopathy has been reported with this drug.

Authority Required (STREAMLINED)

13718

Clinically definite relapsing-remitting multiple sclerosis

Treatment criteria:

- Must be treated by a neurologist.

Clinical criteria:

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

natalizumab 150 mg/mL injection, 2 x 1 mL syringes

13825P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	604.89	Tysabri [BD]

natalizumab 300 mg/15 mL injection, 15 mL vial

9505G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	604.89	Tysabri [BD]

OCRELIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

7699

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Authority Required (STREAMLINED)

7386

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

ocrelizumab 300 mg/10 mL injection, 10 mL vial

11242Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*16,656.36	Ocrevus [RO]

ocrelizumab 920 mg/23 mL injection, 23 mL vial

15120T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	16,656.36	Ocrevus SC [RO]

UBLITUXIMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

7386

Multiple sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

Treatment criteria:

- Must be treated by a neurologist.

Ublituximab 150 mg/6 mL injection, 6 mL vial

15175Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
3	0	0.00	*11,583.00	Briumvi [FW]

UBLITUXIMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

7699

Multiple sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; **OR**
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

Treatment criteria:

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

Ublituximab 150 mg/6 mL injection, 6 mL vial

15176R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	0	0.00	*15,444.00	Briumvi [FW]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Note Authority applications for increased repeats may be approved by Services Australia to provide sufficient doses for the relevant treatment phase.

Authority Required

18805

Severe Crohn disease

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must not have achieved an adequate response to a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must not have achieved an adequate response to prior treatment with a thiopurine at a clinically optimised dose for 3 or more consecutive months; **OR**
- Patient must not have achieved an adequate response to methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of not achieving an adequate response to prior systemic therapy; **OR**
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below; **OR**
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of not achieving an adequate response to prior systemic therapy as specified below.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) nominated as the response criteria; and

(c) if applicable, details of intestinal inflammation marker/s; and

(d) if applicable, the CDAI score and the date of assessment; and

(e) the date of the most recent clinical assessment.

Evidence of not achieving an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant contraindications or precautions in the TGA-approved Product Information, please provide details at the time of application. Patients must attempt to trial alternate conventional therapies that are not contraindicated.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Authority Required

18906

Severe Crohn disease

Treatment Phase: Initial 2 (change or recommencement of treatment after a break in targeted therapy of less than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle; **OR**
- Patient must have been eligible for prior PBS-subsidised treatment with a targeted therapy for this condition in this treatment cycle, **AND**
- Patient must have either: (i) not previously received this drug for this condition in the current treatment cycle, (ii) previously received this drug and demonstrated/maintained an adequate clinical response.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, the CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment; and

(d) details of the most recent targeted therapy in the current treatment cycle, including the date and duration of treatment.

If a patient was eligible for prior PBS-subsidised treatment with a targeted therapy for this condition but did not receive PBS-subsidised treatment at the time, the application must provide a declaration that the patient met all 'Initial 1' eligibility requirements when targeted therapy treatment commenced. The following information must also be provided at the time of application:

(a) the baseline CDAI score and the date of assessment; and/or

(b) details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to

treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18863

Severe Crohn disease

Treatment Phase: Initial 3 (recommencement of treatment after a break in targeted therapy of more than 12 months)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a targeted therapy for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised targeted therapy for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 while off treatment with targeted therapy; **OR**
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; and evidence of flared disease while off treatment with targeted therapy; **OR**
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and evidence of flared disease while off treatment with targeted therapy.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

Evidence of flared disease must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

(i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or

(ii) faeces: higher than normal lactoferrin or calprotectin level; or

(iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Authority Required

18806

Severe Crohn disease

Treatment Phase: Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient

Clinical criteria:

- Patient must be receiving treatment with this drug for this condition where treatment was initiated as a paediatric patient via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program), **AND**
- Patient must have met the paediatric PBS eligibility criteria for initial treatment with a targeted therapy treatment for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) if applicable, the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend beyond 24 weeks.

A patient may only qualify for PBS-subsidised treatment under this restriction once. For continuing PBS-subsidised treatment, patients must qualify under the Continuing treatment criteria.

Authority Required

18759

Severe Crohn disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug (in any form) as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; **OR**
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient; **OR**
- Patient must have demonstrated an adequate response to treatment with this drug (in any form).

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) if applicable, current CDAI score and the date of assessment; and

(b) if applicable, details (date, unique identifying number/code or provider number) of the pathology or diagnostic imaging test(s) or details of intestinal inflammation marker/s used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy; and

(c) the date of the most recent clinical assessment.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised targeted therapy was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A maximum quantity and number of repeats of this drug consisting of one vial of 300 mg per dose, with up to 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested through the Balance of supply treatment phase PBS restriction. Under no circumstances will approvals be granted for treatment that would otherwise extend the continuing treatment period.

Authority Required

18807

Severe Crohn disease

Treatment Phase: Balance of supply

Clinical criteria:

- Patient must have received insufficient treatment with this drug for this condition under any relevant initial or continuing restriction (Initial 1, Initial 2, Initial 3, Continuing, or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment), **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment or Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient treatment.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

vedolizumab 300 mg injection, 1 vial

10390W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	2,802.43	Entyvio [TK]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing of targeted therapies under the Pharmaceutical Benefits Scheme (PBS) for benefits with a stated indication of: 'Severe Crohn disease'. For PBS administration, the term targeted therapy includes biological and targeted synthetic disease modifying anti-rheumatic drugs.

A patient is eligible for PBS-subsidised treatment with only one targeted therapy at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1, Initial 2 patients who are accessing PBS-subsidised treatment for the first time, Initial 3 or transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient type restriction. Treatment must not continue with the same targeted therapy if it has not provided an adequate response as defined in the continuing treatment phase. A patient may trial different targeted therapies within a cycle; however, if all available targeted therapies have been trialled and have not provided an adequate response, the treatment cycle ends and a 12-month PBS exclusion period applies.

The 12-month break is measured from the date of the last PBS approval for a targeted therapy in the most recent cycle to the date of first initial treatment application under the next treatment cycle.

If a new targeted therapy with a different pharmacological mechanism of action becomes available on the PBS during a 12-month break, a patient may be prescribed the newly listed targeted therapy through the Initial 2 treatment phase, if they have never received that medicine previously. If the newly listed targeted therapy does not provide an adequate response, the treatment cycle ends and the 12-month break recommences. This will not be considered a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

Initial 1 - use when the patient has never received a targeted therapy for this indication.

Baseline disease activity and inadequate response to conventional therapies must be demonstrated.

Initial 2 - use when an alternative targeted therapy is being prescribed for this indication, or when the patient has previously been treated with this targeted therapy and treatment is resuming after a break of less than 12 months.

Baseline disease activity and inadequate response to conventional therapies do not need to be re-demonstrated; however, an assessment of response to the preceding supply must be provided if a response has been demonstrated.

Initial 3 - use when treatment is resuming after an absence of PBS subsidy for at least 12 months.

Baseline disease activity must be demonstrated; however, a re-trial of conventional therapies is not required.

Transitioning from non-PBS supply commenced as a paediatric patient - use when the patient is receiving non-PBS-subsidised treatment with a targeted therapy for this condition and has been initiated on treatment on the same targeted therapy as a paediatric patient (prior to 18 years of age) via non-PBS pathways (e.g. compassionate access or public hospital individual patient use program).

Continuing treatment - use when patient has demonstrated an adequate response to the preceding supply and/or when the dose is being increased. Continuing treatment authority scripts must not be written on the same day as Initial treatment authority applications.

Balance of supply - use when the full amount of the preceding supply was not provided. This phase provides the remaining quantity that could have been obtained under the preceding authority approval or where additional time is required for an adequate response to be demonstrated.

Recency of assessments:

Where possible, all related assessment documentation (including Crohn Disease Activity Index calculations, pathology tests and diagnostic imaging studies) should be within 4 weeks of the date of authority application but no longer than 4 weeks following cessation of the most recent treatment.

Authority Required

18760

Severe Crohn disease

Treatment Phase: Initial 4 (additional dose at week 10)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in this treatment cycle, **AND**
- Patient must have received 3 doses of initial treatment under either: (i) Initial 1, (ii) Initial 2, (iii) Initial 3, **AND**
- Patient must not have achieved an adequate response to this drug after a total of 3 doses of initial treatment under either: (i) Initial 1, (ii) Initial 2, (iii) Initial 3.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Population criteria:

- Patient must be at least 18 years of age.

A maximum quantity and number of repeats to provide for an additional dose of this drug consisting of one vial of 300 mg, with one dose to be administered at week 10, will be authorised.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition within the same treatment cycle. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

Patient must be assessed as having an inadequate response to the drug after completing an initial infusion regimen at 0, 2, and 6 weeks and prior to 10 weeks.

vedolizumab 300 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14630B	1	0	0.00	2,802.43	Entyvio [TK]

VEDOLIZUMAB

Note Special Pricing Arrangements apply.

Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3

biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

Authority Required

15933

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; **OR**
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15910

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15844

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; **OR**
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

Population criteria:

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

15923

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; **OR**
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

Population criteria:

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15909

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a gastroenterologist (code 87); **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; **OR**
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

vedolizumab 300 mg injection, 1 vial

10384M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	2,802.43	Entyvio [TK]

VEDOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

19210

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 (new patient)

Clinical criteria:

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; **OR**
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- The treatment must be initiated in combination with standard of care antibiotic, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore and the date of assessment; and

(b) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

Authority Required

19112

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 (Recommencement of treatment after a break in targeted therapy)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have previously received this drug for this condition and demonstrated/maintained an adequate clinical response, **AND**
- The treatment must be initiated in combination with standard of care antibiotic, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) details of the most recent targeted therapy for this condition [date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

(a) Ischaemia;

(b) Crohn's disease (CD) or CD of the pouch;

(c) Irritable pouch syndrome;

(d) Predominant cuffitis;

(e) Pouch stricture or pouch fistula;

(f) Active infection;

(g) NSAIDs;

(h) Coeliac disease.

Authority Required

19113

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 14 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (recommencement of treatment after a break in targeted therapy) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Authority Required

19155

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised targeted therapy treatment for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application.

Treatment criteria:

- Must be treated by a gastroenterologist; **OR**
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology]; **OR**
- Must be treated by a consultant physician [general medicine specialising in gastroenterology].

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

A patient who does not demonstrate a response to treatment will not be eligible for further PBS-subsidised treatment with this drug for this condition. The patient will be considered not to have responded to treatment if a response assessment is not completed. A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as treatment failure.

vedolizumab 300 mg injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14670D	1	2	0.00	2,802.43	Entyvio [TK]

Mammalian target of rapamycin (mTOR) kinase inhibitors

EVEROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5554

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

everolimus 250 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5738B	2	5	0.00	*303.86	[a] Certican [NV]	[a] Everocan [CR]

everolimus 500 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5739C	2	5	0.00	*530.42	[a] Certican [NV]	[a] Everocan [CR]

everolimus 750 microgram tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5740D	4	5	0.00	*1,591.24	[a] Certican [NV]	[a] Everocan [CR]

everolimus 1 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5737Y	4	5	0.00	*2,121.68	[a] Certican [NV]	[a] Everocan [CR]

SIROLIMUS

Caution Careful monitoring of patients is mandatory.

Authority Required (STREAMLINED)

5795

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

Clinical criteria:

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

Caution Careful monitoring of patients is mandatory.

sirolimus 500 microgram tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9747B	2	5	0.00	*587.54	Rapamune [PF]

sirolimus 1 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9549N	2	5	0.00	*1,175.04	Rapamune [PF]

sirolimus 1 mg/mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9550P	2	5	0.00	*924.02	Rapamune [PF]

sirolimus 2 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9548M	2	5	0.00	*2,350.12	Rapamune [PF]

Complement inhibitors

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14754

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; **OR**
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of kidney transplant if applicable (especially if required due to aHUS);

(7) An inclusion of the individual consequences of recurrent disease, if applicable;

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

A maximum of up to 80 weeks of eculizumab treatment (or 104 weeks if switching C5 inhibitors during the course of initial and continuing treatment) is allowed under this restriction, however an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14805

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; **OR**
- Patient must have severe TMA-related neurological impairment; **OR**
- Patient must have severe TMA-related gastrointestinal impairment; **OR**
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; **OR**
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); **OR**
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14799

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS if applicable;

(6) A history of multiple episodes of aHUS following the treatment break, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

Authority Required

14793

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14753

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised ravulizumab (all phases) - loading dose

Clinical criteria:

- Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 24 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

eculizumab 300 mg/30 mL injection, 30 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10183Y	1	5	0.00	5,358.60	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17651

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

Clinical criteria:

- Patient must be planning pregnancy; **OR**
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17626

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**

- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority Required

17602

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**

- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Authority Required

17697

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17693

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

eculizumab 300 mg/30 mL injection, 30 mL vial

12877R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
6	5	0.00	*32,151.60	Soliris [XI]

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14781

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**

- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Evidence of active and progressing TMA is defined by the following:

(1) a platelet count of less than 150x10^9/L; and evidence of two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range;

OR

(2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA;

AND

(3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;

(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

eculizumab 300 mg/30 mL injection, 30 mL vial

10191J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	5,358.60	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.

Note This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17675

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

Clinical criteria:

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

eculizumab 300 mg/30 mL injection, 30 mL vial

12900Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	5,358.60	Soliris [XI]

ECULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Note Services Australia will contact the prescriber by telephone after a written application has been submitted.

Authority Required

14792

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Balance of Supply

Clinical criteria:

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

14750

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement - Balance of Supply

Clinical criteria:

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI).

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

eculizumab 300 mg/30 mL injection, 30 mL vial

10190H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	0.00	5,358.60	Soliris [XI]

ECULIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17684

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - initial 1 (new patient) induction doses

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**

- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17673

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)

Clinical criteria:

- Patient must be planning pregnancy; **OR**
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17630

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Switching from PBS-subsidised pegcetacoplan or iptacopan - induction doses

Clinical criteria:

- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

eculizumab 300 mg/30 mL injection, 30 mL vial

12840T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
8	0	0.00	*42,868.80	Soliris [XI]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17647

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under 'Initial 1' (new untreated patient) or 'Initial 2' (switching from a Complement 5 (C5) inhibitor), **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17598

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First continuing treatment', 'Return' criteria, or 'Grandfather' treatment restrictions, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

Authority Required

17599

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement 1 (Complement 5 (C5) inhibitor inexperienced patients)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2025, **AND**
- Patient must not have received any treatment for this condition prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a diagnosis of PNH established by flow cytometry prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had PNH granulocyte clone size equal to or greater than 10% prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug; **OR**
- Patient must have had recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Authority Required

17622

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangement 2 (Complement 5 (C5) inhibitor experienced patients)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 December 2025, **AND**
- Patient must have had PNH granulocyte clone size equal to or greater than 10% within the last 3 months prior to commencing non-PBS-subsidised treatment with this drug, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating non-PBS-subsidised treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must have been in combination with one C5 inhibitor for a period of 4 weeks during initiation of therapy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a grandfathered patient must qualify under the Subsequent continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13185Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	4,343.86	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17683

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab post pregnancy or from one of the PBS-subsidised therapies for this condition, for reasons other than post pregnancy

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan or iptacopan for pregnancy (induction doses)' criteria; **OR**
- Patient must have received prior PBS-subsidised treatment with at least one drug listed for this condition and must be returning to pegcetacoplan treatment for reasons other than post pregnancy, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)
For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13175K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,343.86	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.
Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority Required

17623

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from a Complement 5 (C5) inhibitor)

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)
(iv) Reticulocytes (x10^9/L)
(v) Neutrophils (x10^9/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

13180Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,343.86	Empaveli [ZO]

PEGCETACOPLAN

Caution This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17601

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new untreated patient)

Clinical criteria:

- Patient must not have received prior treatment with any of the PBS-subsidised therapies listed for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

Population criteria:

- Patient must be at least 18 years of age.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

pegcetacoplan 1.08 g/20 mL injection, 20 mL vial

15127E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	4,343.86	Empaveli [ZO]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18135

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18423

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Non-loading/maintenance doses)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**

- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18238

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18137

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 March 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15244H	1	2	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15225H	1	2	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18132

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18131

Bridging therapy for generalised myasthenia gravis (gMG)

Treatment Phase: Loading dose

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication ('bridging therapy for gMG').

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18237

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**

- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18133

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients (Loading dose)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Where loading doses of ravulizumab are required, additional authority prescriptions may be requested and approved in the same day.

At the time of authority application, medical practitioners must request the appropriate number of vials for a single loading dose based on the patient's weight, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15245J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15258C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

14748

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Balance of Supply - maintenance doses

Clinical criteria:

- Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note Services Australia will contact the prescriber by telephone after a written application has been submitted.

Authority Required

18260

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 72 weeks of ravulizumab treatment in total under this restriction; **OR**
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of kidney transplant if applicable (especially if required due to aHUS);

(7) An inclusion of the individual consequences of recurrent disease, if applicable;

(8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18262

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; **OR**
- Patient must have severe TMA-related neurological impairment; **OR**
- Patient must have severe TMA-related gastrointestinal impairment; **OR**
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; **OR**
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); **OR**
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18153

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

Clinical criteria:

- Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; **OR**
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18155

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

Clinical criteria:

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply of a C5 inhibitor treatment was commenced, the patient: (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample not confounded by any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing C5 inhibitor treatment; (iv) had clinical features of active organ damage or impairment, **AND**
- Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients;

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay;

(6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised C5 inhibitor treatment;

(7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised C5 inhibitor treatment;

(8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for the balance of the current treatment phase. 8 weeks of treatment and up to 2 repeats according to the specified dosage in the approved Product Information (PI) may be sought.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

13785M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

13797E

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note See the following article/website for details on Expanded Disability Status Scale (EDSS): https://www.ncbi.nlm.nih.gov/books/NBK222389/.

Authority Required

16368

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

Treatment criteria:

- Must be treated by a neurologist; **OR**
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

ravulizumab 300 mg/3 mL injection, 3 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14784D	1	2	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14758R	1	2	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note See the following article/website for details on Expanded Disability Status Scale (EDSS): https://www.ncbi.nlm.nih.gov/books/NBK222389/.

Authority Required

17055

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Initial treatment - loading dose

Clinical criteria:

- Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG), **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must have experienced at least one relapse in the last 12 months while receiving treatment with rituximab; **OR**
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; **OR**

- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a neurologist; **OR**
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

The authority application must be in writing and must include all of the following:

(1) details of the proposed authority prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:

(i) the patient's Expanded Disability Status Scale (EDSS) score; and

(ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ravulizumab 300 mg/3 mL injection, 3 mL vial

14759T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

14783C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18134

Acute severe generalised myasthenia gravis (gMG)

Treatment Phase: Non-loading/maintenance doses

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have received a loading dose of this drug for this indication; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient dose of the drug, according to the specified dosage in the TGA approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the TGA PI will not be approved.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ravulizumab 300 mg/3 mL injection, 3 mL vial

15255X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	1	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

15246K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	1	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17631

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)
(ii) Platelets ($x10^9$/L)
(iii) White Cell Count ($x10^9$/L)
(iv) Reticulocytes ($x10^9$/L)
(v) Neutrophils ($x10^9$/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

Note This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

Authority Required

17629

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)
(ii) Platelets ($x10^9$/L)
(iii) White Cell Count ($x10^9$/L)
(iv) Reticulocytes ($x10^9$/L)
(v) Neutrophils ($x10^9$/L)
(vi) Granulocyte clone size (%)
(vii) Lactate Dehydrogenase (LDH)
(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
(ix) the LDH: ULN ratio (in figures, rounded to one decimal place)

Authority Required

17609

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; **OR**
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12884D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12883C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum number of repeats may be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

Note Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

Authority Required

18351

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Initial (new patient) loading dose

Clinical criteria:

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than 30x10^9/L and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than 150x10^9/L; and evidence of at least two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients;

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;

(6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

e) Exclusion of alternative causes of TMA;

f) History of renal or other organ transplant (if any);

g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

Authority Required

18350

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised eculizumab (all phases) - loading dose

Clinical criteria:

- Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; **OR**

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; **OR**
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommencement of treatment' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) Details of the proposed prescription(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Authority Required

18283

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

Clinical criteria:

- Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; AND (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10^9/L); OR (iii) TMA-related organ impairment including on recent biopsy.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:
(1) Details of the proposed prescription(s);
(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
(3) A measurement of body weight at the time of application;
(4) Results of genetic testing, if not previously submitted;
(5) A family history of aHUS if applicable;
(6) A history of multiple episodes of aHUS following the treatment break, if applicable;
(7) A history of kidney transplant if applicable (especially if required due to aHUS);
(8) An inclusion of the individual consequences of recurrent disease;
(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;
(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;
(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.
Two authority prescription forms will be required to cover for the 26 weeks of recommencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

Note At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

Note A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

Note Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

ravulizumab 300 mg/3 mL injection, 3 mL vial

13808R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

13809T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	0	0.00	24,105.11	Ultomiris [XI]

RAVULIZUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

17605

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

Clinical criteria:

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**

- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded; **OR**
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10^9/L)

(iii) White Cell Count (x10^9/L)

(iv) Reticulocytes (x10^9/L)

(v) Neutrophils (x10^9/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17610

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

Clinical criteria:

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; **OR**
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; **OR**

- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets ($x10^9$/L)

(iii) White Cell Count ($x10^9$/L)

(iv) Reticulocytes ($x10^9$/L)

(v) Neutrophils ($x10^9$/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH: ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

Authority Required

17606

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

Authority Required

17630

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Switching from PBS-subsidised pegcetacoplan or iptacopan - induction doses

Clinical criteria:

- Patient must have received PBS-subsidised treatment with either: (i) pegcetacoplan, (ii) iptacopan for this condition, **AND**
- Patient must have developed resistance or intolerance to either: (i) pegcetacoplan, (ii) iptacopan, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Must be treated by a haematologist; **OR**
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the proposed prescription(s); and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

ravulizumab 300 mg/3 mL injection, 3 mL vial

12898W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	6,574.12	Ultomiris [XI]

ravulizumab 1.1 g/11 mL injection, 11 mL vial

12856P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	24,105.11	Ultomiris [XI]

ZILUCOPLAN

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59clOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18232

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:

(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);

(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18378

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18129

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18128

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 April 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15316D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	21,395.05	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15286M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	29,521.05	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15325N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	41,658.62	Zilbrysq [UC]

ZILUCOPLAN

Caution C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18319

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**
- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Zilucoplan 16.6 mg/0.416 mL injection, 28 x 0.416 mL syringes

15276B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	21,395.05	Zilbrysq [UC]

Zilucoplan 23 mg/0.574 mL injection, 28 x 0.574 mL syringes

15303K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	29,521.05	Zilbrysq [UC]

Zilucoplan 32.4 mg/0.81 mL injection, 28 x 0.81 mL syringes

15287N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	41,658.62	Zilbrysq [UC]

Neonatal fragment crystallizable receptor (FcRn) inhibitors

ROZANOLIXIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18232

Bridging therapy for generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for 3 months; (ii) oral corticosteroids for 3 months; (iii) a thymectomy, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must not receive more than 6 months of bridging treatment with any gMG biological agent under this PBS indication.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing and must include:
(a) the MG-ADL and MGC score after 3-months of remission-inducing treatments (include the date the assessments were conducted);
(b) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy].
If the application is submitted through HPOS form upload or mail, it must include the following:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

Authority Required

18378

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Initial treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not have received treatment with a gMG biologic within 3 months prior to the first authority application for this indication (i.e. in treatment refractory setting); **OR**
- Patient must be considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per initial authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

Patients who are considered to have deteriorating gMG disease while on a treatment break with a gMG biologic may qualify with 9 months of remission inducing treatments (rather than 12 months).
The authority application must be via the Online PBS Authorities System, or in writing and must include:
(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];
(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessments were conducted).
If the application is submitted through HPOS form upload or mail, it must include:
(1) details of the proposed prescription; and
(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18129

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Continuing treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with a gMG biological agent for this PBS indication, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- The treatment must provide no more than 6 months of therapy per continuing authority application.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include the MG-ADL and MGC scores assessed from the most recent course of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

18789

Treatment refractory generalised myasthenia gravis (gMG)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfathering treatment - Treatment refractory gMG patients

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must have had a thymectomy, **AND**
- Patient must have had a MG-ADL score of 6 (or higher) and a MGC score of 10 (or higher), despite having undergone 2 of the following 3 remission inducing treatments: (i) NS-IST for a minimum of 12 months, (ii) oral corticosteroids for a minimum of 12 months, (iii) a thymectomy, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MG-ADL score of at least 2 points from baseline, **AND**
- Patient must have demonstrated a clinical improvement based on a decrease in MGC score of at least 3 points from baseline, **AND**
- The treatment must provide no more than 6 months of therapy under this restriction.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System, or in writing and must include:

(a) details of remission-inducing treatments [date commencement and duration of drug therapy including drug names and dosages, and/or date of the thymectomy];

(b) the baseline MG-ADL and MGC scores assessed after completing the 12 months of remission-inducing treatments (include the date the assessment was conducted);

(c) the MG-ADL and MGC scores assessed from the most recent course of treatment demonstrating clinical improvement to treatment (include the date the assessment was conducted).

If the application is submitted through HPOS form upload or mail, it must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A retrospective assessment for one of the MGC score or MG-ADL score after completing the 12 months remission inducing treatments can be accepted for grandfathered patients in cases where it was not conducted prior to commencing non-PBS-subsidised treatment for this indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15391C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
18	2	0.00	*219,189.60	Rystiggo [UC]

ROZANOLIXIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Treatment switching:

Switching between gMG biological agents is permitted. Treatment switching should be limited to when a patient moves between different treatment settings, i.e. moving from 'acute severe gMG' to 'bridging therapy for gMG' [(1) to (2)]; or moving from 'bridging therapy for gMG' to 'treatment refractory gMG' [(2) to (3)].

In the acute severe (1) or bridging therapy (2) settings a patient may switch to an alternate gMG biological agent if they are experiencing an intolerance or toxicity necessitating treatment withdrawal. Patients can switch by requalifying through the relevant restrictions. Only a balance of the time limits specified within the relevant treatment setting will be approved i.e. the remaining of the 3 months (acute severe gMG); or 6 months (bridging therapy for gMG) after accounting for the treatment of the previous gMG biologic.

In the treatment refractory setting (3), a patient may switch to an alternate gMG biological agent via either:

a) the initial restriction if they have trialled a different gMG biologic, but did not respond to treatment; or

b) the continuing restriction if they have trialled a different gMG biological agent and have responded to treatment.

Mark any remaining unused repeat prescriptions as "cancelled".

Note Definitions for the purposes of administering this restriction.

Where the term **'gMG biological agent'** is referenced in this restriction, it refers to ravulizumab, rozanolixizumab and zilucoplan.

A non-steroidal immunosuppressant (NS-IST) is one of the following:

(i) azathioprine,

(ii) ciclosporin,

(iii) cyclophosphamide,

(iv) methotrexate,

(v) mycophenolate

(vi) tacrolimus

The Myasthenia Gravis Foundation of America (**MGFA**) Disease Classification can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/MGFA%20Classification.pdf

The Myasthenia Gravis Composite (**MGC**) scoring profile can be accessed at https://www.criteria.blood.gov.au/NeurologicalScales#MGC

The Myasthenia Gravis-Activities of Daily Living (**MG-ADL**) scoring profile can be accessed at https://myasthenia.org/wp-content/uploads/Portals/0/Files/MG%20ADL%20Profile.pdf?ver=YQFk2umcz59cIOttpxZ-3w%3D%3D

The following are settings and time limits where a gMG biological agent are PBS subsidised:

(1) Three months of acute treatment - 'acute severe gMG'.

(2) Six months of bridging therapy - 'bridging therapy for gMG'.

(3) Continuous therapy - 'treatment refractory gMG'.

A patient may transition sequentially from one phase to another where all criteria are met e.g. (1) to (2) to (3) but cannot return to an earlier treatment setting.

Authority Required

18319

Acute severe generalised myasthenia gravis (gMG)

Clinical criteria:

- Patient must have a diagnosis of MGFA Disease Class II to IV, **AND**
- Patient must have a positive serology for acetylcholine receptor (AChR) binding autoantibodies, **AND**
- Patient must not be experiencing a myasthenic crisis, **AND**
- Patient must be considered by the treating clinician to have rapidly deteriorating gMG disease in the absence of immediate treatment with a gMG biological agent, **AND**
- Patient must not be receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) immunoglobulin, (iii) plasma exchange (PLEX), (iv) rituximab for this condition, **AND**
- Patient must be receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST); **OR**
- Patient must be commencing treatment with an NS-IST within 2 weeks; **OR**
- Patient must have had a thymectomy, **AND**
- Patient must be receiving concomitant treatment with an oral corticosteroid, **AND**
- Patient must not receive more than 3 months of total treatment with gMG biological agents under this PBS indication ('acute severe gMG'), **AND**
- Patient must not have accessed a prior PBS-subsidised gMG biological agent; **OR**

- Patient must have developed an intolerance/toxicity to a PBS-subsidised gMG biological agent necessitating a change in treatment.

Treatment criteria:

- Must be treated by a prescriber who is either: (i) a neurologist; (ii) a clinical immunologist with expertise in the treatment of myasthenia gravis; **OR**
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with an agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

The authority application must be via the Online PBS Authorities System or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include the following:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Rozanolixizumab 280 mg/2 mL injection, 2 mL vial

15398K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	18	1	0.00	*219,189.60	Rystiggo [UC]

Other immunosuppressants

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19067

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12034J	1	3	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12061T	1	3	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12026Y	1	3	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14592B	1	3	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12059Q	1	3	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

13782

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12985K	1	2	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12988N	1	2	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12988N					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12991R	1	2	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14616G	1	2	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12979D	1	2	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

13813

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12039P	1	1	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12057N	1	1	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12062W	1	1	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14633E	1	1	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
12036L	1	1	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

14362

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 5 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13636Q	1	2	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13661B	1	2	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13641Y	1	2	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
14608W	1	2	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13630J	1	2	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

17414

Untreated multiple myeloma

Treatment Phase: Triple combination therapy consisting of daratumumab, lenalidomide and dexamethasone

Treatment criteria:

- Patient must be undergoing concurrent treatment with daratumumab obtained through the PBS for the treatment of transplant ineligible, newly diagnosed multiple myeloma, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

lenalidomide 5 mg capsule, 21

15106C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

15067B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

15078N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

15095L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

15104Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19062

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and

(3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and

(4) details of the basis of the diagnosis of progressive disease or failure to respond; and

(5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13805

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

5783J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

5784K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

5785L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

14588T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

5786M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
				Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19119

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and

(2) confirmation of ineligibility for prior stem cell transplant; and

(3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826
HOBART TAS 7001

Authority Required

13787

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

14632D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	769.49	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19076

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) the date the autologous stem cell transplant was performed; and

(3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13804

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 28

11967W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	497.00	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 28

11968X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	651.10	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 28

11964Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	784.18	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19079

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine - the percentage of plasma cells; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple

myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13811

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

lenalidomide 5 mg capsule, 14

12035K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	248.50	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 14

12070G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	325.55	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 14

12012F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	392.09	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 14

14623P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	0.00	505.16	Lenalide [JU]

lenalidomide 25 mg capsule, 14

12019N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	512.99	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

19065

Myelodysplastic syndrome

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.

Classification of a patient as red blood cell transfusion dependent requires that:

(i) the patient has been transfused within the last 8 weeks; and

(ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and

(b) details (date, unique identifying number/code or provider number) of the full blood examination report; and

(c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and

(d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

19066

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**

- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

(i) a haemoglobin level taken within the last 4 weeks; and

(ii) the date of the last transfusion; and

(iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

lenalidomide 5 mg capsule, 21

2799H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

2802L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

LENALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed:

- Revlimid - i-access program;
- Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program;
- Lenalide - Juno Connected™;
- Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program.

Authority Required

18932

Relapsed or refractory follicular lymphoma

Clinical criteria:

- The treatment must be in combination with rituximab and tafasitamab; **OR**
- The treatment must be in combination with tafasitamab.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

lenalidomide 5 mg capsule, 21

15487D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	372.75	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 10 mg capsule, 21

15451F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	488.33	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 15 mg capsule, 21

15452G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	588.14	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]
					Lenalidomide Sandoz [SZ]	Revlimid [BQ]

lenalidomide 20 mg capsule, 21

15428B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	0.00	757.74	[a] Lenalide [JU]	[a] Lenalidomide Sandoz [SZ]

POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority Required

13746

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and

(2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13755

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

pomalidomide 1 mg capsule, 21

13803L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	396.09	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 2 mg capsule, 21

13788Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	706.08	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 3 mg capsule, 21

10406Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	1,059.12	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 4 mg capsule, 21

10387Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	0	0.00	1,412.15	Pomalidomide Sandoz [SZ]	Pomolide [JU]

POMALIDOMIDE

Caution This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalidomide Sandoz - Pregnancy Prevention Program.

Authority Required

13757

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority Required

13768

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

pomalidomide 1 mg capsule, 14

13794B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	264.06	Pomolide [JU]

pomalidomide 2 mg capsule, 14

13815D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	2	0.00	470.72	Pomolide [JU]

pomalidomide 3 mg capsule, 14

12666P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	706.08	Pomalidomide Sandoz [SZ]	Pomolide [JU]

pomalidomide 4 mg capsule, 14

12665N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	0.00	941.43	Pomalidomide Sandoz [SZ]	Pomolide [JU]

THALIDOMIDE

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Authority Required (STREAMLINED)

5914

Multiple myeloma

Caution Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

Note Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

thalidomide 50 mg capsule, 28

9566L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	0	0.00	*1,061.40	Thalomid [BQ]

thalidomide 100 mg capsule, 28

9667T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	0	0.00	*1,061.38	Thalomid [BQ]

MUSCULO-SKELETAL SYSTEM

MUSCLE RELAXANTS

MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

Other centrally acting agents

BACLOFEN

Authority Required (STREAMLINED)

7152

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority Required (STREAMLINED)

7134

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority Required (STREAMLINED)

7153

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority Required (STREAMLINED)

7148

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule

11195F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
2	0	0.00	*611.38	Sintetica Baclofen Intrathecal [BZ]

BACLOFEN

Note Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

6925

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

Authority Required (STREAMLINED)

6939

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

Authority Required (STREAMLINED)

6940

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

Authority Required (STREAMLINED)

6911

Severe chronic spasticity

Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; **OR**
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5617P	10	0	0.00	*762.70	[a] Bacthecal [DZ]	[a] Lioresal Intrathecal [NV]

baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11126N	1	0	0.00	762.70	[a] Sintetica Baclofen Intrathecal [BZ]

DRUGS FOR TREATMENT OF BONE DISEASES

DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

Bisphosphonates

PAMIDRONATE DISODIUM

Authority Required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

pamidronate disodium 60 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5669J	1	2	0.00	55.26	Pamisol [PF]

PAMIDRONATE DISODIUM

Authority Required (STREAMLINED)

4433

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

Authority Required (STREAMLINED)

5218

Multiple myeloma

Authority Required (STREAMLINED)

5291

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

pamidronate disodium 90 mg/10 mL injection, 10 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5670K	1	11	0.00	82.89	Pamisol [PF]

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

14735

Adjuvant management of breast cancer

Population criteria:

- Patient must be post-menopausal.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
13773X	1	0	0.00	45.72	[a] DEZTRON [DZ]	[a] Zoledronate-DRLA 4 [RZ]
					[a] Zoledronic Acid Accord [OC]	

ZOLEDRONIC ACID

Authority Required (STREAMLINED)

5735

Multiple myeloma

Authority Required (STREAMLINED)

5605

Bone metastases

Clinical criteria:

- The condition must be due to breast cancer.

Authority Required (STREAMLINED)

5703

Bone metastases

Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

Authority Required (STREAMLINED)

5704

Hypercalcaemia of malignancy

Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

zoledronic acid 4 mg/5 mL injection, 5 mL vial

9653C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	11	0.00	45.72	[a] APO-Zoledronic Acid [TX]	[a] DEZTRON [DZ]
				[a] Zoledronate-DRLA 4 [RZ]	[a] Zoledronic Acid Accord [OC]
				[a] Zometa [SA]	

Other drugs affecting bone structure and mineralization

BUROSUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

13377

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a documented confirmation of PHEX pathogenic variant; **OR**
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

18953

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

burosumab 10 mg/mL injection, 1 mL vial

13140N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	3,999.00	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

13145W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	7,998.00	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

13155J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	11,997.00	Crysvita [KO]

BUROSUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18982

Tumour-induced osteomalacia

Treatment Phase: Initial treatment - New patient

Clinical criteria:

- Patient must have a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not be a candidate for curative surgical resection as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Prescribers should, where possible, rule out all other non-hereditary forms of FGF-23 related hypophosphataemia such as Fanconi syndrome, iron-infusion associated hypophosphataemia or post renal transplantation hypophosphataemia, prior to initiating patients on burosumab treatment for this condition.

Authority Required

18950

Tumour-induced osteomalacia

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

Authority Required

18952

Tumour-induced osteomalacia

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2026, **AND**
- Patient must have, prior to initiating treatment with this drug, a confirmed diagnosis of hypophosphataemia in tumour-induced osteomalacia demonstrated by the presence of all of the following: (i) chronic clinical symptoms of fatigue, bone pain, muscle weakness and/or (pseudo) fractures; (ii) elevated (or inappropriately normal) serum or plasma FGF-23 levels above the mean of the assay-specific reference range; (iii) a serum phosphate concentration below the age adjusted lower limit of normal; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine, **AND**
- Patient must not have been a candidate for curative surgical resection, prior to initiating treatment with this drug, as a result of either: (i) inability to locate the causative tumour using all available functional imaging technologies; (ii) inability to completely resect the causative tumour due to size, anatomical location, or other patient contraindications or comorbidities; **OR**
- Patient must have had demonstrated persistent hypophosphataemia despite complete surgical resection of the suspected causative tumour prior to initiating treatment with this drug, **AND**
- Patient must have achieved normalisation in serum phosphate levels; **OR**
- The condition must have been reviewed by a second specialist physician with expertise in the management of this condition, confirming that continuing therapy is clinically required.

Treatment criteria:

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

burosumab 10 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15422Q	1	5	0.00	3,999.00	Crysvita [KO]

burosumab 20 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15434H	1	5	0.00	7,998.00	Crysvita [KO]

burosumab 30 mg/mL injection, 1 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15480R	1	5	0.00	11,997.00	Crysvita [KO]

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

Other drugs for disorders of the musculo-skeletal system

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

14459

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; **OR**
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**

- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. *Muscle & Nerve* 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. *PLoS ONE* 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. *American Journal of Respiratory and Critical Care Medicine* 166(1), pp 111-117

The National Hearth Foundation of Australia has 6MWT test standardised instructions and recording forms located at: https://www.heartonline.org.au/resources/documents-and-links#exercise

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. *Muscle & Nerve* 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. *Neurology* April (15 Supplement) P4.452

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13068T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18094

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**

- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Failure to gain weight appropriate for age,

(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

18078

Spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

Treatment criteria:

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

Note Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13052Y	1	3	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

18077

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in a child

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,

(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

18101

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

Treatment criteria:

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

Note Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13083N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18073

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**

- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:
i) Onset before 6 months of age; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Defined signs and symptoms of type II SMA are:
i) Onset between 6 and 18 months; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Weakness in trunk righting/derotation; or
v) Hypotonia; or
vi) Absence of deep tendon reflexes; or
vii) Failure to gain weight appropriate for age; or
viii) Any active chronic neurogenic changes; or
ix) A compound muscle action potential below normative values for an age-matched child.
Defined signs and symptoms of type IIIa SMA are:
i) Onset between 18 months and 3 years of age; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Application for authorisation of initial treatment must be in writing and must include:
(a) details of the proposed prescription; and
(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
(i) specification of SMA type (I, II or IIIa); and
(ii) sign(s) and symptom(s) that the patient has experienced; and
(iii) patient's age at the onset of sign(s) and symptom(s).

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

11363C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

15069

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist

medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**

- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

11378W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18110

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

12177X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

14433

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

13084P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

15112

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

14095W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Authority Required

18076

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

14099C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,500.00	Spinraza [BD]

NUSINERSEN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note For the next authority application after this application, continue treatment through the 'Treatment phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA listing' under the indication: 'Spinal muscular atrophy (SMA)'.

Authority Required

18053

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with one of: (i) Type 1 SMA, or, (ii) pre-symptomatic SMA

Clinical criteria:

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

Population criteria:

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy; **OR**
- Patient must have a prior authority approval for any drug PBS-listed for pre-symptomatic SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for one of the following:

(i) Symptomatic Type 1 SMA; or

(ii) Pre-symptomatic SMA treated with nusinersen.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:
1. Rolls from side to side on back;
2. Child holds head erect for at least 3 seconds unsupported;
3. Sitting, but with assistance;
4. Sitting without assistance:
(a) Child sits up straight with the head erect for at least 10 seconds;
(b) Child does not use arms or hands to balance body or support position.
5. Hands and knees crawling:
(a) Child alternately moves forward or backwards on hands and knees;
(b) The stomach does not touch the supporting surface;
(c) There are continuous and consecutive movements at least 3 in a row.
6. Standing with assistance:
(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;
(b)The body does not touch the stable object, and the legs support most of the body weight;
(c) Child thus stands with assistance for at least 10 seconds.
7. Standing alone:
(a) Child stands in upright position on both feet (not on the toes) with the back straight;
(b) The leg supports 100% of the child's weight;
(c) There is no contact with a person or object;
(d) Child stands alone for at least 10 seconds.
8. Walking with assistance:
(a) Child is in an upright position with the back straight;
(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
(c) One leg moves forward while the other supports part of the body weight;
(d) Child takes at least 5 steps in this manner.
9. Walking alone:
(a) Child takes at least 5 steps independently in upright position with the back straight;
(b) One leg moves forward while the other supports most of the body weight;
(c) There is no contact with a person or object.

Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i).

Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.

nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial

12972R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	3	0.00	104,500.00	Spinraza [BD]

ONASEMNOGENE ABEPARVOVEC

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the *Gene Technology Act 2000*.

The following website provides a list of accredited organisations and may update without notice:

https://www.ogtr.gov.au/what-weve-approved/accredited-organisations

Authority Required

18211

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs/symptoms of Type 1 SMA specified below; **OR**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

Population criteria:

- Patient must be no older than 9 months of age
- Patient must have symptomatic Type 1 SMA; **OR**
- Patient must have pre-symptomatic SMA.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribing Instructions:

In the relevant PBS Authority Application form, specify the following:

(i) the SMA type being treated: symptomatic Type 1 SMA, or, pre-symptomatic SMA;

(ii) for Type 1 SMA, the signs/symptoms that the patient has experienced, together with the patient's age at the onset of these signs/symptoms.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

If the condition is pre-symptomatic SMA, confirm that there is genetic test finding that substantiates the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

18213

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

Clinical criteria:

- The treatment must be given concomitantly with best supportive care for this condition, **AND**

- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

Treatment criteria:

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

Population criteria:

- Patient must be no older than 9 months of age
- Patient must have symptomatic Type 1 SMA; **OR**
- Patient must have pre-symptomatic SMA with 1-2 copies of SMN2 gene.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for one of the following:

(i) Symptomatic Type 1 SMA; or

(ii) Pre-symptomatic SMA with 1-2 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

12951P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

12977B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

12942E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

12976Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

12975X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

12956X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

12964H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack

12955W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

12958B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

12940C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

12950N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

12963G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

12941D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

12952Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials

12957Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials

12961E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials

12971Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials

12962F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials

12973T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials

12954T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials

12974W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials

12949M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	2,527,773.87	Zolgensma [NV]

ONASEMNOGENE ABEPARVOVEC

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

Note Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

Note Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the *Gene Technology Act 2000*.

The following website provides a list of accredited organisations and may update without notice:

https://www.ogtr.gov.au/what-weve-approved/accredited-organisations

Authority Required

16045

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

Population criteria:

- Patient must be no older than 9 months of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Authority Required

15989

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

Clinical criteria:

- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

Treatment criteria:

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

Population criteria:

- Patient must be no older than 9 months of age
- Patient must have pre-symptomatic SMA with 3 copies of the SMN2 gene.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for pre-symptomatic SMA with 3 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13671M	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13670L	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13672N	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
13680B	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

13677W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

13662C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack

13666G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack

13663D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

13669K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

13682D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

13683E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

13681C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

13679Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

13668J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials

13674Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials

13678X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials

13665F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials

13667H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials

13664E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials

13675R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials

13673P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials

13676T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	‡1	0	0.00	2,527,773.87	Zolgensma [NV]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18087

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Clinical criteria:

- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

i) Onset between 6 and 18 months; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Weakness in trunk righting/derotation; or

v) Hypotonia; or

vi) Absence of deep tendon reflexes; or

vii) Failure to gain weight appropriate for age; or
viii) Any active chronic neurogenic changes; or
ix) A compound muscle action potential below normative values for an age-matched child.
Defined signs and symptoms of type IIIa SMA are:
i) Onset between 18 months and 3 years of age; and
ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
iii) Proximal weakness; or
iv) Hypotonia; or
v) Absence of deep tendon reflexes; or
vi) Failure to gain weight appropriate for age; or
vii) Any active chronic neurogenic changes; or
viii) A compound muscle action potential below normative values for an age-matched child.
Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.
Application for authorisation of initial treatment must be in writing and must include:
(a) details of the proposed prescription; and
(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
(i) specification of SMA type (I, II or IIIa); and
(ii) sign(s) and symptom(s) that the patient has experienced; and
(iii) patient's age at the onset of sign(s) and symptom(s).
The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
(iv) 2 years of age and older weighing 20 kg or more: 5 mg
In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:
1 unit where (i) applies;
2 units where (ii) applies;
3 units where (iii) applies;
3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12614X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

15986

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

14646W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

Authority Required

15095

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12606L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the next authority application after this application, continue treatment through the 'Treatment phase: Continuing treatment' under the indication: 'Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)'.

Authority Required

18357

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA

Clinical criteria:

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

Population criteria:

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:

1. Rolls from side to side on back;

2. Child holds head erect for at least 3 seconds unsupported;

3. Sitting, but with assistance;

4. Sitting without assistance:

(a) Child sits up straight with the head erect for at least 10 seconds;

(b) Child does not use arms or hands to balance body or support position.

5. Hands and knees crawling:

(a) Child alternately moves forward or backwards on hands and knees;

(b) The stomach does not touch the supporting surface;

(c) There are continuous and consecutive movements at least 3 in a row.

6. Standing with assistance:

(a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;
(b)The body does not touch the stable object, and the legs support most of the body weight;
(c) Child thus stands with assistance for at least 10 seconds.
7. Standing alone:
(a) Child stands in upright position on both feet (not on the toes) with the back straight;
(b) The leg supports 100% of the child's weight;
(c) There is no contact with a person or object;
(d) Child stands alone for at least 10 seconds.
8. Walking with assistance:
(a) Child is in an upright position with the back straight;
(b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
(c) One leg moves forward while the other supports part of the body weight;
(d) Child takes at least 5 steps in this manner.
9. Walking alone:
(a) Child takes at least 5 steps independently in upright position with the back straight;
(b) One leg moves forward while the other supports most of the body weight;
(c) There is no contact with a person or object.
Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i).
Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.
The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
(iv) 2 years of age and older weighing 20 kg or more: 5 mg
In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:
1 unit where (i) applies;
2 units where (ii) applies;
3 units where (iii) applies;
3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12943F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18118

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA)

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**

- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13655Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18090

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**

- Patient must not have received PBS-subsidised gene therapy.

Population criteria:

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

14659M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	0	0.00	10,841.89	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18479

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 5 mg tablet, 28

15275Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18307

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- Patient must not have received PBS-subsidised gene therapy.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

Population criteria:

- Patient must be between 2 and 18 years of age and weigh 20 kg or more.

Defined signs and symptoms of type I SMA are:

i) Onset before 6 months of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

i) Onset between 6 and 18 months; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Weakness in trunk righting/derotation; or

v) Hypotonia; or

vi) Absence of deep tendon reflexes; or

vii) Failure to gain weight appropriate for age; or

viii) Any active chronic neurogenic changes; or

ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

i) Onset between 18 months and 3 years of age; and

ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or

iii) Proximal weakness; or

iv) Hypotonia; or

v) Absence of deep tendon reflexes; or

vi) Failure to gain weight appropriate for age; or

vii) Any active chronic neurogenic changes; or

viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) specification of SMA type (I, II or IIIa); and

(ii) sign(s) and symptom(s) that the patient has experienced; and

(iii) patient's age at the onset of sign(s) and symptom(s).

risdiplam 5 mg tablet, 28

15281G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18369

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Population criteria:

- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

risdiplam 5 mg tablet, 28

15297D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

18306

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

Population criteria:

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

risdiplam 5 mg tablet, 28

15310T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

Authority Required

14392

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19th birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13631K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,525.67	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18356

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Failure to gain weight appropriate for age,

(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13654P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	7	0.00	*32,525.67	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. *Muscle & Nerve* 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. *PLoS ONE* 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. *American Journal of Respiratory and Critical Care Medicine* 166(1), pp 111-117

The National Hearth Foundation of Australia has 6MWT test standardised instructions and recording forms located at: https://www.heartonline.org.au/resources/documents-and-links#exercise

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. *Muscle & Nerve* 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. *Neurology* April (15 Supplement) P4.452

Authority Required

14420

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

Treatment criteria:

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; **OR**
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19th birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; **OR**
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13656R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,525.67	Evrysdi [RO]

risdiplam 5 mg tablet, 28

15327Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18225

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

Population criteria:

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19th birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Failure to gain weight appropriate for age,

(vi) Any active denervation or chronic neurogenic changes found on electromyography,

(vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

(2) which of the above (i to vii) (at least 1) were present during childhood,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 5 mg tablet, 28

15273W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

18308

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC)
- Patient must be 2 years of age or older, and weigh 20 kg or more.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,

(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,

(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

risdiplam 5 mg tablet, 28

15309R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	25,297.74	Evrysdi [RO]

RISDIPLAM

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

Authority Required

18197

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

Population criteria:

- Patient must be of an age that is prior to their 19th birthday at the time of this authority application
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3rd birthday, but before their 19th birthday (SMA type IIIB/IIIC).

Treatment criteria:

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; **OR**
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; **OR**
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Clinical criteria:

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; **OR**
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

(i) Failure to meet or regression in ability to perform age-appropriate motor milestones,

(ii) Proximal weakness,

(iii) Hypotonia,

(iv) Absence of deep tendon reflexes,

(v) Any active denervation or chronic neurogenic changes found on electromyography,

(vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:
(1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
(2) which of the above (i to vi) (at least 1) were present after their 3rd birthday, but before their 19th birthday,
(3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.
The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.
The approved Product Information recommended dosing is as follows:
(i) 16 days to less than 2 months of age: 0.15 mg/kg
(ii) 2 months to less than 2 years of age: 0.20 mg/kg
(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
(iv) 2 years of age and older weighing 20 kg or more: 5 mg
In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:
1 unit where (i) applies;
2 units where (ii) applies;
3 units where (iii) applies;
3 units where (iv) applies.

risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13633M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡3	5	0.00	*32,525.67	Evrysdi [RO]

NERVOUS SYSTEM

ANTI-PARKINSON DRUGS

DOPAMINERGIC AGENTS

Dopa and dopa derivatives

FOSLEVODOPA + FOSCARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)
16812
Advanced Parkinson disease
Treatment criteria:
- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

Clinical criteria:
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

14914Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*4,976.68	Vyalev [VE]

FOSLEVODOPA + FOSCARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)
16853
Advanced Parkinson disease
Treatment criteria:
- Must be treated by a specialist physician; **OR**
- Must be treated by a physician who has consulted a specialist physician with expertise in the management of Parkinson's disease.

Clinical criteria:
- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- Patient must require continuous administration of foslevodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2,400 mg of foslevodopa.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

foslevodopa 2.4 g/10 mL + foscarbidopa 120 mg/10 mL injection, 7 x 10 mL vials

14924L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
8	5	0.00	*9,953.36	Vyalev [VE]

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

10375

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; **OR**
- Patient must require a total daily dose of more than 2000 mg of levodopa.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
9743T	8	5	0.00	*11,536.00	Duodopa [VE]

LEVODOPA + CARBIDOPA

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

10138

Advanced Parkinson disease

Clinical criteria:

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

Note Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11913B	4	5	0.00	*5,768.00	Duodopa [VE]

Dopamine agonists

APOMORPHINE

Authority Required (STREAMLINED)

11385

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5610G	36	5	0.00	*6,029.64	Movapo [TD]

apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
10950H	36	5	0.00	*8,017.20	Movapo PFS [TD]

APOMORPHINE

Authority Required (STREAMLINED)

10863

Parkinson disease

Clinical criteria:

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11093W	18	5	0.00	*7,427.34	Apomine Solution for Infusion [IT]

Apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
15111H	18	5	0.00	*7,427.34	MOVAPO POD [TD]

APOMORPHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

10863
Parkinson disease
Clinical criteria:
- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11477C	20	5	0.00	*2,588.00	[a] Movapo Pen [TD]

apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11672H	20	5	0.00	*2,588.00	[a] Apomine Intermittent [IT]

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority Required (STREAMLINED)
5015
Schizophrenia
Treatment Phase: Initial treatment
Treatment criteria:
- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:
- Patient must be non-responsive to other neuroleptic agents; **OR**
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.
The name of the consulting psychiatrist should be included in the patient's medical records.
A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11433R	‡1	0	0.00	135.00	Versacloz [DU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)
5015
Schizophrenia
Treatment Phase: Initial treatment
Treatment criteria:
- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

Clinical criteria:
- Patient must be non-responsive to other neuroleptic agents; **OR**
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.
The name of the consulting psychiatrist should be included in the patient's medical records.
A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5628F	2	0	0.00	*55.50	Clopine 25 [DU] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5626D	2	0	0.00	*110.98	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5630H	1	0	0.00	135.00	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5629G	2	0	0.00	*208.08	Clopine 100 [DU] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
5627E	2	0	0.00	*416.16	Clopine 200 [DU]	Clozitor [JU]

PSYCHOANALEPTICS

ANTIDEPRESSANTS

Other antidepressants

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16422

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 16 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14813P	8	0	0.00	*4,706.56	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16477

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 8 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 actuations

14816T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
8	0	0.00	*2,353.28	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16419

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 12 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations

14821C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*3,529.92	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16460

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 4 units of nasal spray is intended for a dosage of 28 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 actuations

14822D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*1,176.64	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16454

Treatment resistant major depression

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must have been inadequately responsive to at least two oral anti-depressant drug therapies.

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The following must apply if reinitiating treatment:

(i) at least four-week gap from last treatment course to reinitiation of treatment; and

(ii) evidence, documented in the patient's medical record using a structured rating scale, of significant clinical therapeutic benefit of the prior course of treatment with esketamine; and

(iii) evidence, documented in the patient's medical record using a structured rating scale, of a relapse in depression.

The listed quantity of 24 units of nasal spray is intended for a dosage of 84 mg per treatment administration in the induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 3 x 2 actuations

14835T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	8	0	0.00	*7,059.84	Spravato [JC]

ESKETAMINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16470

Treatment resistant major depression

Treatment Phase: Non-induction treatment

Clinical criteria:

- The treatment must be to continue existing PBS-subsidised treatment for this indication, **AND**
- The treatment must not exceed each of: (i) an administered dose beyond 84 mg, (ii) a quantity of drug, after accounting for repeat prescriptions plus different pack sizes where prescribed, that would exceed a quantity sufficient to treat the patient for 24 weeks, **AND**
- Patient must have demonstrated adequate response to treatment with esketamine after the 4-week induction and every 6 months thereafter as evaluated by a structured clinical rating scale (evidence of scores and justification of demonstration of response must be retained in the patient's medical records).

Treatment criteria:

- Must be treated by a psychiatrist, where prescribing must also be completed by the treating psychiatrist, **AND**
- Patient must be undergoing supervision at an accredited treatment centre for the administration of esketamine.

The listed quantity of 8 units of nasal spray is intended for a dosage of 56 mg per treatment administration in the non-induction treatment setting.

esketamine 28 mg/2 actuations nasal spray, 2 x 2 actuations

14837X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	4	5	0.00	*2,353.28	Spravato [JC]

OTHER NERVOUS SYSTEM DRUGS

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

VUTRISIRAN

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16446

Hereditary transthyretin amyloidosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing, **AND**
- Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; **OR**
- Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV).

Treatment criteria:

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

Population criteria:

- Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy
- Patient must be at least 18 years of age.

PND scores in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage I - Sensory disturbances but preserved walking capability;

Stage II - Impaired walking capacity but able to walk without stick or crutches;

Stage IIIA - Walking with help of one stick or crutch;

Stage IIIB - Walking with help of two sticks or crutches;

Stage IV - Confined to wheelchair or bedridden.

FAP stage in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage 1 - Unimpaired ambulation;

Stage 2 - Assistance with ambulation required;

Stage 3 - Wheelchair-bound or bedridden.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

16434

Hereditary transthyretin amyloidosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not be permanently bedridden; **OR**
- Patient must not be receiving end-of-life care.

Treatment criteria:

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Vutrisiran 25 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14810L	1	1	0.00	114,121.96	Amvuttra [WM]

RESPIRATORY SYSTEM

DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

Other systemic drugs for obstructive airway diseases

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

benralizumab 30 mg/mL injection, 1 mL pen device

12000N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	3,145.45	Fasenra Pen [AP]

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19128

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

benralizumab 30 mg/mL injection, 1 mL pen device

11995H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	3,145.45	Fasenra Pen [AP]

BENRALIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic

reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19130

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the eosinophil count and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19082

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

benralizumab 30 mg/mL injection, 1 mL pen device

11994G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	4	0.00	3,145.45	Fasenra Pen [AP]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note It is recommended that an application for continuing treatment is submitted at the 28 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

19137

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; **OR**

- Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; **OR**
- Patient must have a fractional exhaled nitric oxide of at least 20 ppb in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment, blood eosinophil count or fractional exhaled nitric oxide measurement must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE, blood eosinophil or the fractional exhaled nitric oxide result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Authority Required

19091

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE, blood eosinophil or fractional exhaled nitric oxide result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

14959H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	1,609.86	[a] Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
15041P	1	7	0.00	1,609.86	[a]	Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note It is recommended that an application for continuing treatment is submitted at the 28 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised treatment with this drug for this condition.

Authority Required

19137

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre in the last 12 months; **OR**
- Patient must have a fractional exhaled nitric oxide of at least 20 ppb in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The initial IgE assessment, blood eosinophil count or fractional exhaled nitric oxide measurement must be no more than 12 months old at the time of application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 28 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the last dose of biological medicine, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab of up to 32 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE, blood eosinophil or the fractional exhaled nitric oxide result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Authority Required

19091

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- Patient must be under the care of the same physician for at least 6 months, **AND**

- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be submitted no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE, blood eosinophil or fractional exhaled nitric oxide result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

14964N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	0.00	1,609.86	[a] Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

15032E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	3	0.00	1,609.86	[a] Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

17073

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

14961K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	0	0.00	1,609.86	[a]	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

14987T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	0	0.00	1,609.86	[a]	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17073

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment, or transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - Balance of Supply in a patient aged 6 to 12 years

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 32 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 32 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing and transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

14963M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	0	0.00	1,609.86	a	Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

14978H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	0	0.00	1,609.86	a	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19136

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12318H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,609.86	Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12302L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,609.86	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19132

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**

- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated;

AND

(ii) treatment with oral corticosteroids as outlined in the clinical criteria.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19133

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have each of: (i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

12293B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	8	0.00	1,609.86	Dupixent [SW]

DUPILUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19181

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19213

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**

- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

12309W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	8	0.00	1,609.86	Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution.

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17009

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) maintenance oral corticosteroid dose; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

Authority Required

17113

Uncontrolled severe asthma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate to determine whether the patient has achieved or sustained an adequate response to non-PBS subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been at least 28 weeks

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of

the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(b) IgE, blood eosinophils or fractional exhaled nitric oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and

(c) date of commencing non-PBS-subsidised treatment with this drug for this condition.

(d) If applicable, maintenance oral corticosteroid dose; and

(e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or

(f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes

14986R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
	1	2	0.00	1,609.86	[a]	Dupixent [SW]

dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices

14988W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
	1	2	0.00	1,609.86	[a]	Dupixent [SW]

DUPILUMAB

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Note Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution.

Authority Required

17009

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must be aged 6 to less than 12 years.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) maintenance oral corticosteroid dose; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

Authority Required

17113

Uncontrolled severe asthma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 September 2025, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist; (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (i) forced expiratory volume (FEV1) reversibility, (ii) airway hyperresponsiveness, (iii) peak expiratory flow (PEF) variability, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to commencement of non-PBS-subsidised treatment with this drug, **AND**
- Patient must have had a documented total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiation of PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**

- Patient must have had a fractional exhaled nitric oxide of at least 20 ppb in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Population criteria:

- Patient must have been aged 6 to less than 12 years prior to starting non-PBS-subsidised treatment with this drug.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

The following initiation criteria indicate failure to achieve adequate control with optimised asthma therapy and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed prior to non-PBS-subsidised treatment with this drug for this condition (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the prior to non-PBS-subsidised treatment with this drug for this condition 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate to determine whether the patient has achieved or sustained an adequate response to non-PBS subsidised treatment, must be conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application if the treatment duration has been at least 28 weeks

All applications for continuing treatment with this biological medicine must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate must be made at around 20 weeks after the first dose of PBS-subsidised treatment with this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The first assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be submitted within 4 weeks of the date of assessment, and no later than 2 weeks prior to the patient completing their current treatment course, to avoid an interruption to supply. Where a response assessment is not undertaken and submitted, the patient will be deemed to have failed to respond to treatment with this drug for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of dupilumab, sufficient for 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) prior optimised asthma drug therapy (date of commencement and duration of therapy); and

(b) IgE, blood eosinophils or fractional exhaled nitric oxide results and date from prior to initiating non-PBS-subsidised treatment with this drug; and

(c) date of commencing non-PBS-subsidised treatment with this drug for this condition.

(d) If applicable, maintenance oral corticosteroid dose; and

(e) If applicable, the Asthma Control Questionnaire (ACQ-5) scores, including the date of assessment of the patient's symptoms; or

(f) If applicable, the Asthma Control Questionnaire interviewer administered version (ACQ-IA) scores, including the date of assessment of the patient's symptoms.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices

15011C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	5	0.00	1,609.86	a	Dupixent [SW]

dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes

15021N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $		Brand Name and Manufacturer
1	5	0.00	1,609.86	a	Dupixent [SW]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

mepolizumab 100 mg/mL injection, 1 mL pen device

12021Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	1,556.10	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required

19200

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have received PBS-subsidised treatment with this biological medicine for this condition, **AND**
- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with the initial PBS authority application, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

The following must be provided in each continuing PBS authority application and be documented in the patient's medical records:

details of the current number and severity of exacerbations compared to baseline levels provided in the initial authority application of this treatment cycle including:

(i) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(ii) number of moderate exacerbations requiring treatment with antibiotics; and

(iii) number of severe exacerbation(s) which required hospitalisation.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority Required

19166

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Grandfather arrangements - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved, prior to commencing non-PBS-subsidised treatment with this drug for this condition, adequate control with at least 3 months of optimised triple inhaled therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- Patient must have both, achieved and sustained an adequate response to this drug, defined as maintenance (i.e. no change); or a reduction in the number of moderate and/or severe exacerbation(s) compared to the baseline levels provided with this authority application, if they received at least 24 weeks of treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to commencing non-PBS-subsidised treatment with this drug for this condition, are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; AND

(ii) details of therapy with a combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement, and duration of therapy prior to commencing non-PBS-subsidised treatment with this drug for this condition); AND

(iii) the baseline exacerbation history which includes:

details of the number and severity of COPD exacerbations experienced in the 12 months immediately prior to commencement of this drug as non-PBS-subsidised therapy for this condition, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation; AND

(iv) the assessment of response to treatment where applicable (for patients who have received at least 24 weeks of treatment), which includes:

details of the current number and severity of COPD exacerbations, compared with the baseline information supplied in this authority application, including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbations requiring hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction.

In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

mepolizumab 100 mg/mL injection, 1 mL pen device

15511J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,556.10	Nucala [GK]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note **TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19128

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

mepolizumab 100 mg/mL injection, 1 mL pen device

12064Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,556.10	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

Authority Required

19092

Uncontrolled chronic obstructive pulmonary disease (COPD)

Treatment Phase: Initial treatment (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**

- Patient must have had at least a 12-month break from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to commencing treatment with this drug in this treatment cycle, **AND**
- Patient must not have achieved adequate control with at least 3 months of an optimised triple inhaler therapy consisting of: (i) long-acting muscarinic antagonist (LAMA); (ii) a long-acting beta-2 agonist (LABA); (iii) an inhaled corticosteroid (ICS), despite formal assessment of and adherence to correct inhaler technique which has been documented in the patient's medical records, **AND**
- Patient must have experienced at least one severe COPD exacerbation, or at least two moderate COPD exacerbations in the 12 months prior to commencing treatment with this drug in this treatment cycle, **AND**
- The treatment must be in combination with all of: (i) LAMA; (ii) LABA; (iii) ICS in an optimised triple inhaler therapy, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician; (ii) general physician experienced in the management of patients with this condition.

For the purpose of administering this restriction, COPD exacerbations in the 12 months prior to starting treatment in this treatment cycle are defined as experiencing:

(i) at least 1 severe COPD exacerbation which required hospitalisation; and/or

(ii) 2 or more moderate COPD exacerbations, of which at least:

(a) one required treatment with systemic corticosteroids; and

(b) one required treatment with systemic corticosteroids or antibiotics.

At least one of the moderate or severe exacerbations must have occurred while the patient was taking all of: (i) LAMA; (ii) LABA; and (iii) ICS in an optimised triple inhaler therapy.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include the following:

(i) the blood eosinophil count and date; and

(ii) details of the optimised triple inhaler therapy with the combination of LAMA, LABA and ICS (name of treatment, dosage, date of commencement and duration of therapy); and

(iii) details of the number and severity of COPD exacerbation(s) experienced in the 12 months prior to commencing treatment with this drug in this treatment cycle including:

(a) number of moderate exacerbations requiring treatment with systemic corticosteroids; and/or

(b) number of moderate exacerbations requiring treatment with antibiotics; and

(c) number of severe exacerbation(s) which required hospitalisation.

The details of the number and the severity of COPD exacerbations are to inform the basis of determining if an adequate response to treatment has been achieved under the continuing treatment restriction. In addition to stating the above details in the authority application, document them in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

mepolizumab 100 mg/mL injection, 1 mL pen device

15525D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	0.00	1,556.10	Nucala [GK]

MEPOLIZUMAB

Note Special Pricing Arrangements apply.

Note For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19139

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the eosinophil count and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19184

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

mepolizumab 100 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
12007Y	1	7	0.00	1,556.10	Nucala [GK]

MEPOLIZUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

Authority Required

19198

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

Clinical criteria:

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; **OR**
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; **OR**
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; **OR**
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

Population criteria:

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

(a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated

(b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

The authority application must be made in writing and must include:

(a) details of the proposed prescription,

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),

(c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,

(d) details (date and treatment) of nasal polyp surgery; or

(e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,

(f) the eosinophil count and date,

(g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

13865

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

Population criteria:

- Patient must be at least 18 years of age.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

mepolizumab 100 mg/mL injection, 1 mL pen device

13237Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,556.10	Nucala [GK]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19163

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Authority Required

19141

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses

for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10967F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	6	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 300 mg/2 mL injection, 2 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14952Y	1	0	0.00	418.14	Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17012

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy), Initial treatment - Initial 2 (Change of treatment), Continuing treatment - Balance of Supply in a patient aged 6 to 12 years

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy) restriction to complete 28 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment - Initial 2 (Change of treatment) restriction to complete 28 weeks of treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial 1 and Initial 2 restriction; **OR**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the Continuing restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11962N

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 150 mg/mL injection, 1 mL syringe

11950Y

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	205.98	Omlyclo [EW]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses

of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 150 mg/mL injection, 1 mL syringe

11828M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	205.98	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14929R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	209.07	[a] Xolair [NV]

OMALIZUMAB

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

15376

Uncontrolled severe asthma

Treatment Phase: Balance of supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; **OR**
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; **OR**
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11846L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14905L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	0	0.00	104.54	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

19214

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

For second and subsequent continuing treatment with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The following information must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

14947Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	102.99	Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL syringe

14948R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	205.98	Omlyclo [EW]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 300 mg/2 mL injection, 2 mL pen device

14906M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	418.14	Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 300 mg/2 mL injection, 2 mL pen device

14885K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	418.14	Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 150 mg/mL injection, 1 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11824H	1	5	0.00	205.98	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14922J	1	5	0.00	209.07	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19080

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11835X	1	5	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
14950W	1	5	0.00	104.54	[a] Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

17096

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**

- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 150 mg/mL injection, 1 mL syringe

11945Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	205.98	Omlyclo [EW]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

17086

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11946R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note **TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required (STREAMLINED)

17085

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have a documented history of either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised dose of this biological medicine so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

At the time of authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) If applicable, the baseline and maintenance oral corticosteroid dose; and

(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or

(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and

(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

14920G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	102.99	Omlyclo [EW]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringe and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**

- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 150 mg/mL injection, 1 mL syringe

10109C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	205.98	[a] Omlyclo [EW]

omalizumab 150 mg/mL injection, 1 mL pen device

14884J	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	7	0.00	209.07	[a] Xolair [NV]

OMALIZUMAB

Note For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines).

Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

Note Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringe and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen device are equivalent for the purposes of substitution.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19083

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) the IgE result and date; and

(e) Asthma Control Questionnaire (ACQ-5) score.

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Authority Required

19161

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (date and duration of treatment) of prior biological medicine treatment; and

(c) the IgE results and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10118M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	7	0.00	102.99	[a] Omlyclo [EW]	[a] Xolair [NV]

omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device

14949T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	104.54	[a] Xolair [NV]

OMALIZUMAB

Caution The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.

Note No increase in the maximum number of repeats may be authorised.

Note For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com

Note The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ASTHMA AND UNCONTROLLED SEVERE ALLERGIC ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines dupilumab for uncontrolled severe asthma and omalizumab for uncontrolled severe allergic asthma. Therefore, where the term 'biological medicine' appears in notes and restrictions, it refers to dupilumab and omalizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicine at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma or uncontrolled severe allergic asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 September 2025 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 2 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma/uncontrolled severe allergic asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of 32 weeks of therapy of dupilumab and a maximum of 28 weeks of therapy of omalizumab. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ, ACQ-IA; 5 item version), systemic corticosteroid dose and time adjusted exacerbation rate, submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsided biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction, provided they meet all of the restriction criteria.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug with the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with either biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsided treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with either 2 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 2 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients (Omalizumab only):

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medication for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19163

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 1 (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma; **OR**
- Patient must have had a break in treatment from the most recently approved PBS-subsidised biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;

AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used),

AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose,

and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine for this condition.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and

(b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(c) the IgE result and date; and

(d) Asthma Control Questionnaire (ACQ-5) score; or

(e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

Authority Required

19141

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Clinical criteria:

- Patient must have received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either: (i) severe asthma, (ii) severe allergic asthma, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 6 to less than 12 years.

Clinical criteria:

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma or severe allergic asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made no more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An Asthma Control Questionnaire (ACQ-5) or Asthma Control Questionnaire interviewer administered version (ACQ-5-IA) assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 24 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 24 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

A patient who fails to demonstrate a response to treatment with this biological medicine will not be eligible to receive further PBS-subsidised treatment with this biological medicine for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 2 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date of the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the IgE result and date; and

(b) Asthma Control Questionnaire (ACQ-5) score; or

(c) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

(d) the details of prior biological medicine treatment including the details of date and duration of treatment; and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

omalizumab 150 mg/mL injection, 1 mL syringe

10973M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	6	0.00	205.98	Omlyclo [EW]

TEZEPELUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For copies of the ACQ and the calculation sheets please contact AstraZeneca Medical Information on 1800 805 342.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19094

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS-subsidised biological medicine therapy)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; **OR**
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater

than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**

- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiating treatment with this drug; **OR**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiating treatment with this drug that has past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the month prior to initiating this drug, AND

(b) while receiving optimised asthma therapy in the 12 months prior to initiating this drug, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

Authority Required

19199

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must be under the care of the same physician for at least 6 months; **OR**
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing biological medicine treatment for severe asthma; **OR**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing biological medicine treatment for severe asthma; **OR**
- Patient must have each of: i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating treatment with a biological medicine for severe asthma, ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

A multidisciplinary severe asthma clinic team comprises of:

(i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and

(b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and

(c) if applicable, the eosinophil count and date; and

(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) if applicable, the IgE result and date; and

(f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

Authority Required

19095

Uncontrolled severe asthma

Treatment Phase: Grandfathering arrangements - Transitioning from non-PBS to PBS-subsidised supply

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this biological medicine for this PBS indication prior to 1 July 2026, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; **OR**
- Patient must have had a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a duration of asthma of at least 1 year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had blood eosinophil count of at least 300 cells per microlitre in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition; **OR**
- Patient must have had total serum human immunoglobulin E of at least 30 IU/mL, measured in the 12 months prior to initiation of non-PBS subsidised treatment with this drug for this condition that had past or current evidence of atopy, documented by either: (i) skin prick testing; or (ii) an in vitro measure of specific IgE no more than 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment with this drug if the patient has received at least 28 weeks of treatment with this drug for this condition, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease.

Population criteria:

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the month prior to starting treatment with this drug, AND

(b) while receiving optimised asthma therapy in the 12 months prior to starting treatment with this drug, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with all eligible biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of tezepelumab sufficient for up to 32 weeks of therapy, at a dose of 210 mg every four weeks.

The following must be provided at the time of application and documented in the patient's medical records:

(a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and

(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and

(c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and

(d) Asthma Control Questionnaire (ACQ-5) score; and

(e) if applicable, the eosinophil count and date; and

(f) if applicable, the IgE result and date.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15403Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	7	0.00	1,671.78	Tezspire [AP]

TEZEPELUMAB

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For copies of the ACQ and the calculation sheets please contact AstraZeneca Medical Information on 1800 805 342.

Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment with each of the biological medicines they are eligible for, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or

(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all eligible biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months, must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

Authority Required

19093

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

Clinical criteria:

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps; (ii) uncontrolled severe allergic asthma; (iii) uncontrolled severe asthma; (iv) uncontrolled chronic obstructive pulmonary disease, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

Population criteria:

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug and should be conducted within 4 weeks of the last dose of biological medicine.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) if applicable, details of maintenance oral corticosteroid dose; and

(b) a completed Asthma Control Questionnaire (ACQ-5) score.

Tezepelumab 210 mg/1.91 mL injection, 1.91 mL pen device

15413F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	1,671.78	Tezspire [AP]

COUGH AND COLD PREPARATIONS

EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

Mucolytics

DORNASE ALFA

Authority Required (STREAMLINED)

5740

Cystic fibrosis

Population criteria:

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

5634

Cystic fibrosis

Clinical criteria:

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; **OR**
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; **OR**
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; **OR**
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

Population criteria:

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

5635

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

Population criteria:

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5704F	2	5	0.00	*1,490.98	Pulmozyme [RO]

MANNITOL

Authority Required (STREAMLINED)

7362

Cystic fibrosis

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

Authority Required (STREAMLINED)

7367

Cystic fibrosis

Clinical criteria:

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

Population criteria:

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

(1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND

(2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

Note It is highly desirable that all patients be included in the national cystic fibrosis patient database.

mannitol 40 mg powder for inhalation, 280 capsules

2015C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
4	5	0.00	*1,789.20	Bronchitol [HT]

OTHER RESPIRATORY SYSTEM PRODUCTS

OTHER RESPIRATORY SYSTEM PRODUCTS

Other respiratory system products

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17970

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17937

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84

12936W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17846

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17971

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 2 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84

13276R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Trikafta [VR]

ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17772

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to elexacaftor/tezacaftor/ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to elexacaftor/tezacaftor/ivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to elexacaftor/tezacaftor/ivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to elexacaftor/tezacaftor/ivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17770

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (&) ivacaftor 59.5 mg granules [28], 56

14227T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Trikafta [VR]

elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (&) ivacaftor 75 mg granules [28], 56

14228W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Trikafta [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16971

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 1 month or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 13.4 mg granules, 56 sachets

14901G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	20,306.25	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority Required

16928

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 1 month or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 13.4 mg granules, 56 sachets

14881F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	20,306.25	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16878

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; **OR**
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (a) the specific CFTR mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Note For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

Authority Required

16876

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

14156C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

11105L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

11098D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

10170G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	20,306.25	Kalydeco [VR]

IVACAFTOR

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Authority Required

16844

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA-approved Product Information. Quote each of the: (a) the specific mutation listed in the TGA-approved Product Information, (b) name of the pathology report provider, (c) date of pathology report, (d) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

16845

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

Clinical criteria:

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be made via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

ivacaftor 25 mg granules, 56 sachets

14155B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 50 mg granules, 56 sachets

14148P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 75 mg granules, 56 sachets

14167P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Kalydeco [VR]

ivacaftor 150 mg tablet, 56

14153X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	1	5	0.00	20,306.25	Kalydeco [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17967

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17933

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 100 mg + ivacaftor 125 mg tablet, 112

11465K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16,921.88	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17934

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17842

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11466L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	16,921.88	Orkambi [VR]

LUMACAFTOR + IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17765

Cystic fibrosis

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17763

Cystic fibrosis

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 1 year of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets

13798F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,921.88	Orkambi [VR]

lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets

11866M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,921.88	Orkambi [VR]

lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets

11851R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
‡1	5	0.00	16,921.88	Orkambi [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17968

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**

- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17969

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11854X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	18,952.50	Symdeko [VR]

TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17844

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

Population criteria:

- Patient must be at least 12 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

(3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and

(4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

Authority Required

17935

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

Population criteria:

- Patient must be at least 12 years of age.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

(1) details of the proposed prescription; and

(2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and

(3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56

11863J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	18,952.50	Symdeko [VR]

VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authorisation under this restriction should be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)

Alternatively applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor, elexacaftor/tezacaftor/ivacaftor and vanzacaftor/tezacaftor/deutivacaftor.

Authority Required

17932

Cystic fibrosis

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have at least one mutation in the CFTR gene that is considered responsive to vanzacaftor/tezacaftor/deutivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Population criteria:

- Patient must be at least 6 years of age.

For the purposes of this restriction, the list of mutations considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor is defined in the TGA approved Product Information (PI). Mutations that are not listed in the TGA approved PI but considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor can be accepted with a confirmation that these patients do not harbour two Class I mutations.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include:

(1) details of the pathology report substantiating the specific mutation considered to be responsive to vanzacaftor/tezacaftor/deutivacaftor as listed in the TGA approved PI - quote each of the: (i) specific mutation, and if the specific mutation is not listed in the TGA approved PI, confirmation that the patient does not harbour two Class I mutations, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient; and

(2) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Authority Required

17769

Cystic fibrosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

Population criteria:

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be via the Online PBS Authorities System, or in writing via HPOS form upload or mail and must include: current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

If the application is submitted through HPOS form upload or mail, it must include:

(i) details of the proposed prescription; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

vanzacaftor 4 mg + tezacaftor 20 mg + deutivacaftor 50 mg tablet, 84

15216W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	21,375.00	Alyftrek [VR]

vanzacaftor 10 mg + tezacaftor 50 mg + deutivacaftor 125 mg tablet, 56

15205G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	21,375.00	Alyftrek [VR]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Iron chelating agents

DEFERASIROX

Authority Required

7385

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**

- Patient must have a median life expectancy exceeding five years.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 90 mg tablet, 30

11519G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

11500G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

11536E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

7385

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

Note A patient's median life expectancy is determined by the severity of their underlying disease.

Note Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

Note Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

deferasirox 125 mg dispersible tablet, 28

11235H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

11239M	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	2	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

11231D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required

7375

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority Required

7374

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 90 mg tablet, 30

11499F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 180 mg tablet, 30

11556F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 360 mg tablet, 30

11533B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

DEFERASIROX

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

7375

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

Authority Required

7374

Chronic iron overload

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

deferasirox 125 mg dispersible tablet, 28

11247Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 250 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
11240N	6	5	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 500 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11234G	6	5	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERASIROX

Authority Required (STREAMLINED)

8328

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority Required (STREAMLINED)

8329

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Authority Required (STREAMLINED)

8326

Chronic iron overload

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoieisis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

Note Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

deferasirox 90 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11534C	6	2	0.00	*87.06	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 125 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5654N	6	2	0.00	*593.70	Deferasirox Juno [JU]

deferasirox 180 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11535D	6	2	0.00	*174.12	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 250 mg dispersible tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
5655P	6	2	0.00	*123.48	Deferasirox Juno [JU]

deferasirox 360 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
11555E	6	2	0.00	*348.24	[a] DEFERAMED [DZ]	[a] Deferasirox ARX [XT]
					[a] Deferasirox Sandoz [SZ]	[a] DEFERASIROX-TEVA [TB]
					[a] Eferas [AF]	[a] Jadenu [NM]
					[a] Pharmacor Deferasirox FC [CR]	

deferasirox 500 mg dispersible tablet, 28

5656Q	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	0.00	*358.08	[a] Deferasirox Juno [JU]	[a] Pharmacor Deferasirox [CR]

DEFERIPRONE

Authority Required (STREAMLINED)

6448

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

Authority Required (STREAMLINED)

6403

Iron overload

Clinical criteria:

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

deferiprone 100 mg/mL oral liquid, 250 mL

5658T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	5	5	0.00	*963.10	Ferriprox [EU]

deferiprone 500 mg tablet, 100

5657R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	3	5	0.00	*1,155.69	Ferriprox [EU]

deferiprone 1 g tablet, 50

11747G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	6	5	0.00	*2,311.38	Ferriprox [EU]

DESFERRIOXAMINE

Authority Required (STREAMLINED)

6394

Disorders of erythropoiesis

Clinical criteria:

- The condition must be associated with treatment-related chronic iron overload.

desferrioxamine mesilate 500 mg injection, 10 vials

5662B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	40	5	0.00	*5,555.20	DBL Desferrioxamine Mesilate [PF]

desferrioxamine mesilate 2 g injection, 1 vial

5661Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	60	5	0.00	*2,614.80	DBL Desferrioxamine Mesilate [PF]

Drugs for treatment of hyperkalemia and hyperphosphatemia

LANTHANUM

Authority Required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

lanthanum 500 mg chewable tablet, 2 x 45

5780F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*330.80	Fosrenol [TK]

lanthanum 750 mg chewable tablet, 6 x 15

5781G	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*499.52	Fosrenol [TK]

lanthanum 1 g chewable tablet, 6 x 15

5782H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*562.34	Fosrenol [TK]

SEVELAMER

Note Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

Authority Required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sevelamer hydrochloride 800 mg tablet, 180

9546K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*317.62	[a] Renagel [GZ]

sevelamer carbonate 800 mg tablet, 180

11855Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	0.00	*277.48	[a] ARX-SEVELAMER [XT]	[a] Sevelamer Lupin [GQ]

SUCROFERRIC OXYHYDROXIDE

Authority Required (STREAMLINED)

5530

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

Clinical criteria:

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; **OR**
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

Treatment criteria:

- Patient must be undergoing dialysis for chronic kidney disease.

sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90

10233N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
	2	5	0.00	*680.00	Velphoro [CS]

Other therapeutic products

DIFELIKEFALIN

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

Authority Required

15171

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**

- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

Treatment criteria:

- Must be treated by a nephrologist.

Population criteria:

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

(i) drug/dialysis related (e.g., opioid-related pruritus);

(ii) drug hypersensitivity or adverse effect; contact dermatitis; allergy;

(iii) differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

(i) optimisation of dialysis;

(ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);

(iii) patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14140F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	2	0.00	540.00	Korsuva [CS]

DIFELIKEFALIN

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Note See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/

Authority Required

15211

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

Treatment criteria:

- Must be treated by a nephrologist; **OR**
- Must be treated by a medical practitioner in consultation with a nephrologist.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14141G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	Brand Name and Manufacturer
1	5	0.00	540.00	Korsuva [CS]

Highly Specialised Drugs Program (Community Access)

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS.....1051

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES.....1051
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SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

HYPOTHALAMIC HORMONES

Somatostatin and analogues

LANREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

17638

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

Clinical criteria:

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

Authority Required (STREAMLINED)

17696

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11736Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*2,728.40	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

LANREOTIDE

Note Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

Authority Required (STREAMLINED)

16024

Acromegaly

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

Clinical criteria:

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**

- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority Required (STREAMLINED)

16055

Acromegaly

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; **OR**
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; **OR**
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

Authority Required (STREAMLINED)

16057

Functional carcinoid tumour

Treatment Phase: Initial treatment

Treatment criteria:

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; **OR**
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

Clinical criteria:

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)

15955

Functional carcinoid tumour

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe

11315M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
2	5	0.00	*1,821.78	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11316N	2	5	0.00	*2,402.22	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11289E	2	5	0.00	*2,728.40	25.00	[a] Mytolac [GH]	[a] Somatuline Autogel [IS]

OCTREOTIDE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)
17634
Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be either: (i) as monotherapy; (ii) in combination with cabozantinib.

Population criteria:

- Patient must be at least 18 years of age.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.
WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11896D	2	5	0.00	*1,308.48	25.00	Sandostatin LAR [NV]

OCTREOTIDE

Authority Required (STREAMLINED)
8197
Acromegaly
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

Authority Required (STREAMLINED)
8208
Functional carcinoid tumour
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

Authority Required (STREAMLINED)
8198
Vasoactive intestinal peptide secreting tumour (VIPoma)
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11501H	2	5	0.00	*865.26	25.00	Sandostatin LAR [NV]

octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11537F	2	5	0.00	*1,145.04	25.00	Sandostatin LAR [NV]

octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11512X	2	5	0.00	*1,308.48	25.00	Sandostatin LAR [NV]

ANTIINFECTIVES FOR SYSTEMIC USE

ANTIVIRALS FOR SYSTEMIC USE

DIRECT ACTING ANTIVIRALS

CABOTEGRAVIR (&) RILPIVIRINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note It is recommended that patients have previously received 4 weeks of PBS-subsidised initial oral lead-in treatment with cabotegravir and rilpivirine.

Authority Required (STREAMLINED)

12636

HIV infection

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

cabotegravir 600 mg/3 mL modified release injection [3 mL vial] (&) rilpivirine 900 mg/3 mL modified release injection [3 mL vial], 1 pack

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12937X NP	1	5	0.00	2,907.84	25.00	Cabenuva [VI]

Nucleosides and nucleotides excl. reverse transcriptase inhibitors

GANCICLOVIR

Authority Required (STREAMLINED)

5000

Cytomegalovirus retinitis

Clinical criteria:

- Patient must be severely immunocompromised, including due to HIV infection.

ganciclovir 500 mg injection, 5 vials

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10328N NP	2	1	0.00	*261.08	25.00	[a] Cymevene [PB]	[a] GANCICLOVIR SXP [XC]

VALGANCICLOVIR

Authority Required (STREAMLINED)

4980

Cytomegalovirus retinitis

Clinical criteria:

- Patient must have HIV infection.

valganciclovir 50 mg/mL powder for oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10277X NP	11	5	0.00	*4,585.52	25.00	Valcyte [PB]

valganciclovir 450 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10306K NP	2	5	0.00	*525.80	25.00	[a] Valganciclovir Sandoz [SZ]	[a] Valganciclovir Viatris [AL]

Protease inhibitors

ATAZANAVIR + COBICISTAT

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

atazanavir 300 mg + cobicistat 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10692R NP	2	5	0.00	*745.40	25.00	Evotaz [BQ]

DARUNAVIR

Note Pharmaceutical benefits that have the forms darunavir tablet 600 mg, 2 x 30 and darunavir tablet 600 mg (as ethanolate), 60 are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

5094

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10329P NP	2	5	0.00	*1,431.28	25.00	[a] Prezista [JC]

darunavir 600 mg tablet, 2 x 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12946J NP	2	5	0.00	*1,254.66	25.00	[a] Darunavir Juno [JU]

DARUNAVIR

Note Pharmaceutical benefits that have the form darunavir tablet 800 mg and pharmaceutical benefits that have the form darunavir tablet 800 mg (as ethanolate) are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

4313

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

darunavir 800 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10367P NP	2	5	0.00	*844.96	25.00	[a] Prezista [JC]

darunavir 800 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
12111K NP	2	5	0.00	*844.96	25.00	[a] Darunavir Juno [JU]

RITONAVIR

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

ritonavir 100 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10273Q NP	24	5	0.00	*682.68	25.00	Norvir [VE]

Nucleoside and nucleotide reverse transcriptase inhibitors

ABACAVIR

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

13920

Human immunodeficiency virus (HIV) infection

Population criteria:

- Patient must be less than 13.00 years of age.

Clinical criteria:

- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must be in combination with other antiretroviral agents.

abacavir 20 mg/mL oral liquid, 240 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10356C NP	8	5	0.00	*588.20	25.00	Ziagen [VI]

ABACAVIR

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

abacavir 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10294T NP	2	5	0.00	*395.74	25.00	Ziagen [VI]

ENTECAVIR

Authority Required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority Required (STREAMLINED)

5036
Chronic hepatitis B infection
Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

entecavir 500 microgram tablet, 30

10279B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*68.20	25.00	[a] ENTAC [LR]	[a] ENTECAVIR APO [GX]
						[a] Entecavir GH [GQ]	[a] ENTECAVIR RBX [RA]
						[a] Entecavir Sandoz [SZ]	[a] Entecavir Viatris [AL]
						[a] ENTECAVIR-WGR [WG]	

ENTECAVIR

Authority Required (STREAMLINED)
5044
Chronic hepatitis B infection
Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; **OR**
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note PBS-subsidised entecavir monohydrate must be used as monotherapy.

Authority Required (STREAMLINED)
5037
Chronic hepatitis B infection
Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note PBS-subsidised entecavir monohydrate must be used as monotherapy.

entecavir 1 mg tablet, 30

10353X	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*102.64	25.00	[a] ENTECAVIR APO [GX]	[a] ENTECAVIR RBX [RA]
						[a] Entecavir Sandoz [SZ]	[a] Entecavir Viatris [AL]
						[a] ENTECAVIR-WGR [WG]	

LAMIVUDINE

Authority Required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

lamivudine 10 mg/mL oral liquid, 240 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10320E NP	8	5	0.00	*495.08	25.00	3TC [VI]

lamivudine 150 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10348P NP	2	5	0.00	*105.56	25.00	[a] 3TC [VI]	[a] Lamivudine Viatris [AL]

lamivudine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10311Q NP	2	5	0.00	*105.56	25.00	[a] 3TC [VI]	[a] Lamivudine Viatris [AL]

LAMIVUDINE

Authority Required (STREAMLINED)

4993

Chronic hepatitis B infection

Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

Authority Required (STREAMLINED)

5036

Chronic hepatitis B infection

Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

lamivudine 100 mg tablet, 28

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10315X NP	2	5	0.00	*62.14	25.00	[a] Zetlam [AF]	
			[B]2.46	*64.60	25.00	[a] Zeffix [RW]	

TENOFOVIR DISOPROXIL

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

10362

Chronic hepatitis B infection

Clinical criteria:

- Patient must be in the third trimester of pregnancy, **AND**
- Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.

Note Treatment is intended to prevent mother-to-child transmission of hepatitis B in the third trimester of pregnancy and to reduce the risk of viral reactivation in the mother up to 12 weeks post-partum.

tenofovir disoproxil phosphate 291 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11978K NP	2	2	0.00	*94.52	25.00	[a] Tenofovir GH [GQ]

tenofovir disoproxil maleate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11982P NP	2	2	0.00	*94.52	25.00	[a] Tenofovir Disoproxil Viatris [AL]

tenofovir disoproxil fumarate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
11992E NP	2	2	0.00	*131.90	25.00	[a] TENOFOVIR ARX [XT]	[a] Tenofovir Sandoz [SZ]

TENOFOVIR DISOPROXIL

Authority Required (STREAMLINED)

6998

HIV infection
Treatment Phase: Initial
Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)
6982
HIV infection
Treatment Phase: Continuing
Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)
6980
Chronic hepatitis B infection
Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.
Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)
6992
Chronic hepatitis B infection
Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; **OR**
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.
Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)
6983
Chronic hepatitis B infection
Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.
Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)
6984
Chronic hepatitis B infection
Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; **OR**
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

Note Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

Note Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

tenofovir disoproxil phosphate 291 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11142K NP	2	5	0.00	*94.52	25.00	[a] Tenofovir GH [GQ]

tenofovir disoproxil fumarate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10310P NP	2	5	0.00	*131.90	25.00	[a] TENOFOVIR ARX [XT]	[a] Tenofovir Sandoz [SZ]

tenofovir disoproxil maleate 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11155D NP	2	5	0.00	*94.52	25.00	[a] Tenofovir Disoproxil Viatris [AL]

ZIDOVUDINE

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

zidovudine 50 mg/5 mL oral liquid, 200 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10361H NP	15	5	0.00	*602.49	25.00	Retrovir [VI]

zidovudine 100 mg capsule, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10266H NP	4	5	0.00	*572.48	25.00	Retrovir [VI]

zidovudine 250 mg capsule, 40

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10360G NP	6	5	0.00	*854.10	25.00	Retrovir [VI]

Non-nucleoside reverse transcriptase inhibitors

ETRAVIRINE

Authority Required (STREAMLINED)

5014

HIV infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

etravirine 200 mg tablet, 60

10301E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*854.30	25.00	Intelence [JC]

NEVIRAPINE

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

nevirapine 10 mg/mL oral liquid, 240 mL

10319D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	10	5	0.00	*1,457.34	25.00	Viramune [BY]

nevirapine 200 mg tablet, 60

10304H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*164.34	25.00	Nevirapine Viatris [AL]

RILPIVIRINE

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

rilpivirine 25 mg tablet, 30

10298B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*540.98	25.00	Edurant [JC]

Integrase inhibitors

CABOTEGRAVIR

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)

12619

HIV infection

Clinical criteria:

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be in combination with rilpivirine tablets, **AND**
- Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine.

cabotegravir 30 mg tablet, 30

12939B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	0	0.00	695.08	25.00	Vocabria [VI]

DOLUTEGRAVIR

Authority Required (STREAMLINED)

4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

dolutegravir 50 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10283F NP	2	5	0.00	*1,302.22	25.00	Tivicay [VI]

RALTEGRAVIR

Authority Required (STREAMLINED)
4512
HIV infection
Treatment Phase: Initial
Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)
4454
HIV infection
Treatment Phase: Continuing
Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

raltegravir 400 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10286J NP	2	5	0.00	*921.52	25.00	Isentress [MK]

raltegravir 600 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11248B NP	2	5	0.00	*921.52	25.00	Isentress HD [MK]

Antivirals for treatment of HIV infections, combinations

ABACAVIR + LAMIVUDINE

Authority Required (STREAMLINED)
4527
HIV infection
Treatment Phase: Initial
Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:
- Patient must be aged 12 years or older
- Patient must weigh 40 kg or more.

Authority Required (STREAMLINED)
4528
HIV infection
Treatment Phase: Continuing
Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

Population criteria:
- Patient must be aged 12 years or older
- Patient must weigh 40 kg or more.

abacavir 600 mg + lamivudine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10357D NP	2	5	0.00	*84.40	25.00	Abacavir/Lamivudine Viatris [AL]

BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMIDE

Authority Required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority Required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

bictegravir 50 mg + emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11649D NP	2	5	0.00	*1,833.44	25.00	Biktarvy [GI]

DARUNAVIR + COBICISTAT

Authority Required (STREAMLINED)

6413

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority Required (STREAMLINED)

6428

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority Required (STREAMLINED)

6377

Human immunodeficiency virus (HIV) infection

Clinical criteria:

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

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darunavir 800 mg + cobicistat 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10903W NP	2	5	0.00	*856.62	25.00	Prezcobix [JC]

DARUNAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR ALAFENAMIDE

Authority Required (STREAMLINED)

10324

HIV infection
Treatment Phase: Initial treatment
Treatment criteria:
- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

Clinical criteria:
- Patient must be antiretroviral treatment naive; **OR**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- The treatment must not be in combination with ritonavir.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

Authority Required (STREAMLINED)
10317
HIV infection
Treatment Phase: Continuing treatment
Treatment criteria:
- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must not be in combination with ritonavir.

Note The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

darunavir 800 mg + cobicistat 150 mg + emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11955F NP	2	5	0.00	*1,783.76	25.00	Symtuza [JC]

DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE

Authority Required (STREAMLINED)
9981
HIV infection
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must be antiretroviral treatment naive.

Authority Required (STREAMLINED)
10116
HIV infection
Treatment Phase: Continuing treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection.

dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10345L NP	2	5	0.00	*1,500.28	25.00	Triumeq [VI]

DOLUTEGRAVIR + LAMIVUDINE

Authority Required (STREAMLINED)
9987
HIV infection
Treatment Phase: Initial treatment
Clinical criteria:
- Patient must be antiretroviral treatment naive, **AND**
- Patient must not have suspected resistance to either antiretroviral component.

Authority Required (STREAMLINED)
11066
HIV infection
Treatment Phase: Continuing or change of treatment
Clinical criteria:
- Patient must have previously received PBS-subsidised therapy for HIV infection.

dolutegravir 50 mg + lamivudine 300 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11843H NP	2	5	0.00	*1,407.56	25.00	Dovato [VI]

DOLUTEGRAVIR + RILPIVIRINE

Authority Required (STREAMLINED)

8214

HIV infection

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Authority Required (STREAMLINED)

8226

HIV infection

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

dolutegravir 50 mg + rilpivirine 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11540J NP	2	5	0.00	*1,718.68	25.00	Juluca [VI]

EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE

Authority Required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority Required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11104K NP	2	5	0.00	*1,947.84	25.00	Odefsey [GI]

EMTRICITABINE + TENOFOVIR ALAFENAMIDE

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11099E NP	2	5	0.00	*1,436.56	25.00	Descovy [GI]

emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11113X NP	2	5	0.00	*1,436.56	25.00	Descovy [GI]

LAMIVUDINE + ZIDOVUDINE

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

lamivudine 150 mg + zidovudine 300 mg tablet, 60

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10284G NP	2	5	0.00	*178.34	25.00	[a] Combivir [VI]	[a] Lamivudine/Zidovudine Viatris 150/300 [AL]

LOPINAVIR + RITONAVIR

Authority Required (STREAMLINED)

4512

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

4454

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

lopinavir 200 mg + ritonavir 50 mg tablet, 120

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10272P NP	2	5	0.00	*948.12	25.00	Kaletra [VE]

lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10327M NP	10	5	0.00	*893.34	25.00	Kaletra [VE]

TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

Authority Required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority Required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11114Y NP	2	5	0.00	*1,947.84	25.00	Genvoya [GI]

TENOFOVIR DISOPROXIL + EMTRICITABINE

Note Pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

Authority Required (STREAMLINED)

6985

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

Authority Required (STREAMLINED)

6986

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

10347N	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*54.96	25.00	[a] CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR]	[a] TENOFOVIR/EMTRICITABINE 300/200 APX [XW]
						[a] TENOFOVIR/EMTRICITABINE 300/200 ARX [XT]	[a] Tenofovir/Emtricitabine Sandoz Pharma 300/200 [HX]

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

11149T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*54.96	25.00	[a] Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL]

tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30

12506F	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*54.96	25.00	[a] Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ

Note Pharmaceutical benefits that have the form Tablet containing tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg and efavirenz 600 mg can be substituted for Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg in the case of a shortage.

Authority Required (STREAMLINED)

4522

HIV infection

Treatment Phase: Initial

Clinical criteria:

- Patient must be antiretroviral treatment naive.

Authority Required (STREAMLINED)

4470

HIV infection

Treatment Phase: Continuing

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

11732L	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*304.16	25.00	[a] Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600 [AL]

tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30

15231P	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	2	5	0.00	*304.16	25.00	[a] Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablet 600 mg/200 mg/300 mg (Camber, USA) [QY]

Other antivirals

MARAVIROC

Authority Required (STREAMLINED)

5008

HIV infection

Clinical criteria:

- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**

- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

maraviroc 150 mg tablet, 60

10318C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*1,276.80	25.00	[a] Celsentri [VI]	[a] Maraviroc Waymade [IX]

maraviroc 300 mg tablet, 60

10355B	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	0.00	*1,276.80	25.00	[a] Celsentri [VI]	[a] Maraviroc Waymade [IX]

MARIBAVIR

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

16735

Cytomegalovirus infection and disease

Clinical criteria:

- Patient must have received a hematopoietic stem-cell transplant; **OR**
- Patient must have received a solid-organ transplant, **AND**
- Patient must have a cytomegalovirus infection or cytomegalovirus disease that is resistant, refractory or intolerant/contraindicated to appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet; **OR**
- Patient must have received and is intolerant to continued use of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, **AND**
- The treatment must be used as monotherapy for this condition under this restriction, **AND**
- Patient must not have previously demonstrated resistance to this drug, **AND**
- Patient must not have cytomegalovirus disease that involves the central nervous system, **AND**
- Patient must not have cytomegalovirus retinitis.

For the purpose of administering this restriction:

(i) A patient is determined to be refractory if after at least two weeks of appropriately dosed ganciclovir, valganciclovir, cidofovir or foscarnet, they fail to achieve a greater than 1log10 decrease in cytomegalovirus DNA level.

(ii) A patient is determined to be resistant by the identification of a genetic alteration that decreases susceptibility to ganciclovir, valganciclovir, cidofovir or foscarnet.

(iii) A patient with Grade 3 neutropenia (an absolute neutrophil count less than 1000 cells per cubic millimetre) or impaired renal function (creatinine clearance less than 50 mL/min) is determined to be intolerant/contraindicated.

maribavir 200 mg tablet, 28

14866K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	4	1	0.00	*28,905.24	25.00	Livtencity [TK]

NERVOUS SYSTEM

PSYCHOLEPTICS

ANTIPSYCHOTICS

Diazepines, oxazepines, thiazepines and oxepines

CLOZAPINE

Authority Required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
11422E	‡1	0	0.00	155.68	25.00	Versacloz [DU]

CLOZAPINE

Note Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed.

Authority Required (STREAMLINED)

4998

Schizophrenia

Treatment Phase: Continuing treatment

Treatment criteria:

- Must be treated by a psychiatrist; **OR**
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

Clinical criteria:

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

clozapine 25 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10289M	2	0	0.00	*71.12	25.00	Clopine 25 [DU] Clozitor [JU]	Clozaril 25 [GO]

clozapine 50 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10302F	2	0	0.00	*129.64	25.00	Clopine 50 [DU]	Clozitor [JU]

clozapine 50 mg/mL oral liquid, 100 mL

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10341G	1	0	0.00	155.68	25.00	Clopine Suspension [DU]

clozapine 100 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10358E	2	0	0.00	*234.94	25.00	Clopine 100 [DU] Clozitor [JU]	Clozaril 100 [GO]

clozapine 200 mg tablet, 100

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10288L	2	0	0.00	*460.66	25.00	Clopine 200 [DU]	Clozitor [JU]

OTHER NERVOUS SYSTEM DRUGS

DRUGS USED IN ADDICTIVE DISORDERS

Drugs used in opioid dependence

BUPRENORPHINE

Note No increase in the maximum number of repeats may be authorised.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)

16009

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 400 microgram sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13310M NP	4	5	0.00	*37.93	25.00	Subutex [IR]

buprenorphine 2 mg sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13336X						
NP	12	5	0.00	*125.25	25.00	Subutex [IR]

buprenorphine 8 mg sublingual tablet, 7

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13337Y						
NP	16	5	0.00	*431.29	25.00	Subutex [IR]

BUPRENORPHINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)
16051
Opioid dependence
Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13328L						
NP	4	5	0.00	*395.81	25.00	Buvidal Weekly [UR]

buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13297W						
NP	4	5	0.00	*395.81	25.00	Buvidal Weekly [UR]

buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13296T						
NP	4	5	0.00	*395.81	25.00	Buvidal Weekly [UR]

buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13314R						
NP	4	5	0.00	*395.81	25.00	Buvidal Weekly [UR]

BUPRENORPHINE

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)
16015
Opioid dependence
Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.

The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13298X						
NP	1	5	0.00	395.84	25.00	Buvidal Monthly [UR]

buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13309L						
NP	1	5	0.00	395.84	25.00	Buvidal Monthly [UR]

buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13302D						
NP	1	5	0.00	395.84	25.00	Buvidal Monthly [UR]

buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe

13303E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	1	5	0.00	395.84	25.00	Buvidal Monthly [UR]

BUPRENORPHINE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)

16050

Opioid dependence

Treatment criteria:

- Must be treated by a health care professional.

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.

The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe

13320C	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	0.00	395.84	25.00	Sublocade [IR]

buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe

13327K	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	‡1	5	0.00	395.84	25.00	Sublocade [IR]

BUPRENORPHINE + NALOXONE

Note No increase in the maximum number of repeats may be authorised.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)

16009

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28

13322E	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	3	5	0.00	*165.33	25.00	Suboxone Film 2/0.5 [IR]

buprenorphine 8 mg + naloxone 2 mg sublingual film, 28

13321D	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
NP	4	5	0.00	*532.17	25.00	Suboxone Film 8/2 [IR]

METHADONE

Note No increase in the maximum number of repeats may be authorised.

Note Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

Authority Required (STREAMLINED)

16083

Opioid dependence

Clinical criteria:

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

methadone hydrochloride 5 mg/mL oral liquid, 1 L

13333R	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	0.84	5	0.00	*46.97	25.00	[a] Aspen Methadone Syrup [AS]	[a] Biodone Forte [MW]

methadone hydrochloride 5 mg/mL oral liquid, 200 mL

13334T	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	4.2	5	0.00	*53.11	25.00	[a] Aspen Methadone Syrup [AS]	[a] Biodone Forte [MW]

OTHER NERVOUS SYSTEM DRUGS

Other nervous system drugs

EDARAVONE

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority Required

16479

Amyotrophic lateral sclerosis

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules

14806G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2	2	0.00	*4,583.24	25.00	Radicava [TB]

EDARAVONE

Caution Hypersensitivity reactions and cases of anaphylaxis have been reported following the administration of edaravone. Patients should be monitored carefully for hypersensitivity reactions following administration. For more information on administration schedule, refer to the approved Therapeutic Goods Administration (TGA) Product Information.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note The ALS Functional Rating Scale - Revised (ALSFRS-R) can be accessed online at:

www.mdcalc.com/calc/10166/revised-amyotrophic-lateral-sclerosis-functional-rating-scale-alsfrs-r or https://neurotoolkit.com/alsfrs-r/

Authority Required

18480

Amyotrophic lateral sclerosis

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be/have been diagnosed by a neurologist, **AND**
- Patient must not have had symptoms for more than 2 years prior to commencing therapy with this drug, **AND**
- Patient must have at least 80 percent of predicted forced vital capacity (FVC) or slow vital capacity (SVC) within the 2 months prior to commencing therapy with this drug, **AND**
- Patient must not require assistance with eating or ambulation prior to commencing treatment with this drug, **AND**
- Patient must have at least two points on each individual item of the ALS Functional Rating Scale - Revised (ALSFRS-R) score prior to commencing therapy with this drug, **AND**
- Patient must not have undergone a tracheostomy, **AND**
- Patient must not have experienced respiratory failure.

The date of diagnosis, the date and results of spirometry (in terms of percent of predicted forced vital capacity or slow vital capacity) must be supplied with the initial authority application.

Prescribers must request a quantity sufficient to cover one month per dispensing, in accordance with the patient's treatment cycle. Prescribers must request a smaller number of units than the listed maximum quantity units if it is adequate for the patient's needs.

Note Patients who are receiving non-PBS-subsidised treatment with this drug (Grandfathered patients) may transition to PBS-subsidised treatment through the initial treatment phase, provided they met the eligibility criteria at the time treatment was commenced. To continue PBS-subsidised treatment, after accessing the initial PBS-subsided therapy, a Grandfathered patient must qualify under the continuing treatment restriction.

edaravone 30 mg/20 mL injection, 10 x 20 mL ampoules

15334C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
2.8000000000000003	0	0.00	*6,396.85	25.00	Radicava [TB]

Index of Manufacturer Codes

Code	Manufacturer
AF	Alphapharm Pty Ltd
AL	Alphapharm Pty Ltd
AN	Amgen Australia Pty Limited
AP	AstraZeneca Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited
BD	Biogen Australia Pty Ltd
BN	Bayer Australia Ltd
BQ	Bristol-Myers Squibb Australia Pty Ltd
BX	BAXTER HEALTHCARE PTY LTD
BY	Boehringer Ingelheim Pty Ltd
BZ	Boucher & Muir Pty Ltd
CR	Pharmacor Pty Limited
CS	Seqirus (Australia) Pty Ltd
DU	Douglas Pharmaceuticals Australia Pty Limited
DZ	Medsurge Healthcare Pty Ltd
EU	Chiesi Australia Pty Ltd
EW	Celltrion Healthcare Australia Pty Ltd
FK	A.Menarini Australia Pty Limited
FW	NEURAXPHARM AUSTRALIA PTY LIMITED
FZ	Pfizer Australia Pty Ltd
GH	Amdipharm Mercury (Australia) Pty Limited
GI	Gilead Sciences Pty Limited
GK	GlaxoSmithKline Australia Pty Ltd
GO	Viatris Pty Ltd
GQ	Generic Health Pty Ltd
GX	Apotex Pty Ltd
GZ	sanofi-aventis Australia Pty Ltd
HQ	Generic Health Pty Ltd
HT	BTC Speciality Health Pty Ltd
HX	Sandoz Pty Ltd
IR	Indivior Pty Ltd
IS	Ipsen Pty Ltd
IT	InterPharma Pty Ltd
IX	Clinect Pty Ltd
JC	Janssen-Cilag Pty Ltd
JO	Juno Pharmaceuticals Pty Ltd
JU	Juno Pharmaceuticals Pty Ltd
KO	KYOWA KIRIN AUSTRALIA PTY LTD
LL	Astellas Pharma Australia Pty Ltd
LM	Link Medical Products Pty Ltd
LQ	Astellas Pharma Australia Pty Ltd
LR	Cipla Australia Pty Ltd
LY	Eli Lilly Australia Pty Ltd
MK	Merck Sharp & Dohme (Australia) Pty Ltd
MW	Biomed Aust Pty Limited
NE	Norgine Pty. Ltd.
NM	Novartis Pharmaceuticals Australia Pty Limited
NV	Novartis Pharmaceuticals Australia Pty Limited
OC	Accord Healthcare Pty. Ltd.
OQ	Organon Pharma Pty Ltd
PB	Pharmaco (Australia) Limited
PF	Pfizer Australia Pty Ltd

Code	Manufacturer
QY	Pro Pharmaceuticals Group Pty. Ltd.
RA	Sun Pharma ANZ Pty Ltd
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RJ	Recordati Rare Diseases Australia Pty. Ltd.
RO	Roche Products Pty Ltd
RW	Arrow Pharma Pty Ltd
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SA	SciGen (Australia) Pty Limited
SW	sanofi-aventis Australia Pty Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Ltd
TD	STADA Pharmaceuticals Australia Pty Limited
TG	ANTENGENE (AUS) PTY. LTD.
TK	Takeda Pharmaceuticals Australia Pty. Ltd.
TN	Medtas Pty Ltd
TQ	Terumo BCT Australia Pty Limited
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
UC	UCB Australia Proprietary Limited
UR	Camurus Pty Ltd
VE	AbbVie Pty Ltd
VI	ViiV Healthcare Pty Ltd
VR	Vertex Pharmaceuticals (Australia) Pty. Ltd.
WG	WAGNER PHARMACEUTICALS PTY LTD
WM	MEDISON PHARMA AUSTRALIA PTY LIMITED
XC	Southern Cross Pharma Pty Ltd
XI	Alexion Pharmaceuticals Australasia Pty Ltd
XN	Southern XP Pty Ltd
XO	Echo Therapeutics Pty Ltd
XT	Arrotex Pharmaceuticals Pty Ltd
XW	Arrotex Pharmaceuticals Pty Ltd
YG	EUGIA PHARMA (AUSTRALIA) PTY LTD
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ZU	Seekwell Pty Ltd

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12173Q (METHOXSALEN)....95
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12177X (NUSINERSEN)....902
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12186J (AMBRISENTAN)....559
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12212R (AMBRISENTAN)....559
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12240F (SELEXIPAG)....591
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12246M (SELEXIPAG)....79
12247N (SELEXIPAG)....591
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12252W (SELEXIPAG)....591
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12257D (SELEXIPAG)....79
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12265M (SELEXIPAG)....591
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12302L (DUPILUMAB)....954
12309W (DUPILUMAB)....961
12310X (DUPILUMAB)....438
12313C (DUPILUMAB)....441
12316F (DUPILUMAB)....434
12318H (DUPILUMAB)....954
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12348X (ADALIMUMAB)....662
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12355G (ADALIMUMAB)....664
12368Y (ADALIMUMAB)....150
12384T (ADALIMUMAB)....152
12396K (ADALIMUMAB)....157
12406Y (ADALIMUMAB)....654
12417M (ADALIMUMAB)....666
12431G (ADALIMUMAB)....669
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12439Q (ADALIMUMAB)....142
12443X (ADALIMUMAB)....142
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12606L (RISDIPLAM)....915
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12787B (TOCILIZUMAB)....252
12791F (TOCILIZUMAB)....764
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12796L (TOCILIZUMAB)....772
12802T (TOCILIZUMAB)....772
12805Y (TOCILIZUMAB)....252
12810F (TOCILIZUMAB)....260
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12839R (METHOXSALEN)....96
12840T (ECULIZUMAB)....836
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12854M (METHOXSALEN)....608
12855N (METHOXSALEN)....96
12856P (RAVULIZUMAB)....866
12864C (ECULIZUMAB)....321
12876Q (METHOXSALEN)....608
12877R (ECULIZUMAB)....830
12883C (RAVULIZUMAB)....860
12884D (RAVULIZUMAB)....860
12895Q (RAVULIZUMAB)....348
12896R (ECULIZUMAB)....324
12897T (RAVULIZUMAB)....348
12898W (RAVULIZUMAB)....866
12899X (ECULIZUMAB)....318
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12943F (RISDIPLAM)....916
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12956X (ONASEMNOGENE ABEPARVOVEC)....907
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13064N (NUSINERSEN).....386
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13084P (NUSINERSEN).....902
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13210G (ADALIMUMAB).....152
13212J (ADALIMUMAB).....664
13228F (ADALIMUMAB).....662
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13231J (RUXOLITINIB).....114
13232K (RUXOLITINIB).....627
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13238R (RUXOLITINIB).....627
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13242Y (MEPOLIZUMAB).....460
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13255P (USTEKINUMAB).....290
13266F (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....509
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13276R (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....1029
13292N (ADALIMUMAB).....154
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13329M (TOCILIZUMAB).....256
13330N (TOCILIZUMAB).....766
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13636Q (LENALIDOMIDE).....878
13639W (RISDIPLAM).....407
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13646F (RISDIPLAM).....403
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13654P (RISDIPLAM).....922
13655Q (RISDIPLAM).....917
13656R (RISDIPLAM).....923
13657T (LENALIDOMIDE).....366
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13659X (RISDIPLAM).....403
13660Y (LENALIDOMIDE).....366
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13662C (ONASEMNOGENE ABEPARVOVEC).....911
13663D (ONASEMNOGENE ABEPARVOVEC).....911
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13665F (ONASEMNOGENE ABEPARVOVEC).....911
13666G (ONASEMNOGENE ABEPARVOVEC).....911
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13668J (ONASEMNOGENE ABEPARVOVEC).....911

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13671M (ONASEMNOGENE ABEPARVOVEC).....910
13672N (ONASEMNOGENE ABEPARVOVEC).....910
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13678X (ONASEMNOGENE ABEPARVOVEC).....911
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13681C (ONASEMNOGENE ABEPARVOVEC).....911
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13683E (ONASEMNOGENE ABEPARVOVEC).....911
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13716X (TOCILIZUMAB).....258
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13725J (ABATACEPT).....643
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13781H (USTEKINUMAB).....795
13784L (RAVULIZUMAB).....342
13785M (RAVULIZUMAB).....854
13786N (RAVULIZUMAB).....342
13788Q (POMALIDOMIDE).....889
13791W (RAVULIZUMAB).....351
13794B (POMALIDOMIDE).....890
13795C (LUMACAFTOR + IVACAFTOR).....519
13797E (RAVULIZUMAB).....854
13798F (LUMACAFTOR + IVACAFTOR).....1039
13802K (RAVULIZUMAB).....351
13803L (POMALIDOMIDE).....889
13804M (USTEKINUMAB).....283
13808R (RAVULIZUMAB).....863
13809T (RAVULIZUMAB).....863
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13812Y (POMALIDOMIDE).....378
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13814C (POMALIDOMIDE).....377
13815D (POMALIDOMIDE).....890
13820J (NATALIZUMAB).....295
13825P (NATALIZUMAB).....807
14090N (NUSINERSEN).....391
14095W (NUSINERSEN).....903
14096X (NUSINERSEN).....392
14099C (NUSINERSEN).....904
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14107L (ELTROMBOPAG).....32
14110P (DIFELIKEFALIN).....530
14112R (ELTROMBOPAG).....544
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14119D (ELTROMBOPAG).....31
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14121F (ELTROMBOPAG).....544
14127M (ELTROMBOPAG).....33
14128N (ELTROMBOPAG).....545
14131R (ELTROMBOPAG).....545
14136B (ELTROMBOPAG).....32
14140F (DIFELIKEFALIN).....1049
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14143J (ELTROMBOPAG).....33
14144K (ELTROMBOPAG).....543
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14156C (IVACAFTOR).....1034
14157D (IVACAFTOR).....516
14158E (IVACAFTOR).....516
14165M (IVACAFTOR).....514
14167P (IVACAFTOR).....1036
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1419Q (TOCILIZUMAB).....265
14227T (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....1031
14228W (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....1031
14229X (TADALAFIL).....88
1423X (TOCILIZUMAB).....265
14240L (TADALAFIL).....94
14271D (TADALAFIL).....606
14279M (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....511
14280N (ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR).....511
14281P (TADALAFIL).....600
14582L (LENALIDOMIDE).....366
14583M (LENALIDOMIDE).....365
14588T (LENALIDOMIDE).....881
14592B (LENALIDOMIDE).....876
14608W (LENALIDOMIDE).....878
14609X (LENALIDOMIDE).....365
14610Y (LENALIDOMIDE).....369
14614E (VEDOLIZUMAB).....302
14615F (LENALIDOMIDE).....373
14616G (LENALIDOMIDE).....877
14623P (LENALIDOMIDE).....885
14624Q (LENALIDOMIDE).....370
14630B (VEDOLIZUMAB).....814
14631C (LENALIDOMIDE).....364
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14633E (LENALIDOMIDE).....877
14639L (RISDIPLAM).....394
14646W (RISDIPLAM).....914
14647X (RISDIPLAM).....398
1464C (TOCILIZUMAB).....265
14659M (RISDIPLAM).....918
14670D (VEDOLIZUMAB).....821
14679N (VEDOLIZUMAB).....309
14745C (RAVULIZUMAB).....344
14746D (RAVULIZUMAB).....344
14758R (RAVULIZUMAB).....855
14759T (RAVULIZUMAB).....856
1476Q (TOCILIZUMAB).....777
14771K (RAVULIZUMAB).....343
14776Q (RAVULIZUMAB).....343
14783C (RAVULIZUMAB).....856
14784D (RAVULIZUMAB).....855
14785E (MACITENTAN + TADALAFIL).....583
14787G (ESKETAMINE).....410
14798W (ESKETAMINE).....410
14806G (EDARAVONE).....1072
14810L (VUTRISIRAN).....934
14811M (ESKETAMINE).....411
14813P (ESKETAMINE).....930
14814Q (ESKETAMINE).....411
14816T (ESKETAMINE).....931

1481Y (TOCILIZUMAB) 777
14821C (ESKETAMINE) 931
14822D (ESKETAMINE) 931
14823E (ESKETAMINE) 412
14828K (MACITENTAN + TADALAFIL) 71
14829L (VUTRISIRAN) 413
1482B (TOCILIZUMAB) 777
14831N (ESKETAMINE) 412
14835T (ESKETAMINE) 932
14837X (ESKETAMINE) 932
14856X (MARIBAVIR) 622
14865J (MARIBAVIR) 110
14866K (MARIBAVIR) 1068
14880E (EFLORNITHINE) 632
14881F (IVACAFTOR) 1032
14882G (OMALIZUMAB) 487
14883H (OMALIZUMAB) 468
14884J (OMALIZUMAB) 1011
14885K (OMALIZUMAB) 997
14888N (FOSLEVODOPA + FOSCARBIDOPA) 407
14894X (EFLORNITHINE) 632
14895Y (OMALIZUMAB) 609
14900F (EFLORNITHINE) 119
14901G (IVACAFTOR) 1032
14902H (IVACAFTOR) 512
14903J (OMALIZUMAB) 99
14904K (OMALIZUMAB) 491
14905L (OMALIZUMAB) 990
14906M (OMALIZUMAB) 994
14910R (EFLORNITHINE) 120
14911T (OMALIZUMAB) 97
14912W (OMALIZUMAB) 465
14913X (OMALIZUMAB) 610
14914Y (FOSLEVODOPA + FOSCARBIDOPA) 927
14915B (FOSLEVODOPA + FOSCARBIDOPA) 407
14919F (OMALIZUMAB) 472
14920G (OMALIZUMAB) 1007
14921H (OMALIZUMAB) 479
14922J (OMALIZUMAB) 999
14923K (OMALIZUMAB) 494
14924L (FOSLEVODOPA + FOSCARBIDOPA) 927
14927P (OMALIZUMAB) 472
14928Q (OMALIZUMAB) 481
14929R (OMALIZUMAB) 988
14930T (OMALIZUMAB) 98
14936D (IVACAFTOR) 512
14937E (OMALIZUMAB) 610
14938F (OMALIZUMAB) 98
14939G (OMALIZUMAB) 470
14940H (OMALIZUMAB) 97
14945N (OMALIZUMAB) 611
14946P (OMALIZUMAB) 610
14947Q (OMALIZUMAB) 992
14948R (OMALIZUMAB) 992
14949T (OMALIZUMAB) 1014
14950W (OMALIZUMAB) 1001
14951X (OMALIZUMAB) 474
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14953B (OMALIZUMAB) 477
14959H (DUPILUMAB) 944
14960J (DUPILUMAB) 424
14961K (DUPILUMAB) 950
14962L (DUPILUMAB) 428
14963M (DUPILUMAB) 952
14964N (DUPILUMAB) 948
14965P (DUPILUMAB) 424
14977G (DUPILUMAB) 430
14978H (DUPILUMAB) 952
14986R (DUPILUMAB) 965
14987T (DUPILUMAB) 950
14988W (DUPILUMAB) 965
14993D (PEGINTERFERON ALFA-2A) 640
14999K (DUPILUMAB) 428
15000L (DUPILUMAB) 431
15011C (DUPILUMAB) 969
15012D (DUPILUMAB) 445
15015G (PEGINTERFERON ALFA-2A) 128
15021N (DUPILUMAB) 969
15022P (DUPILUMAB) 449
15025T (PEGINTERFERON ALFA-2A) 640
15032E (DUPILUMAB) 948
15033F (DUPILUMAB) 449
15034G (DUPILUMAB) 430
15036J (PEGINTERFERON ALFA-2A) 128
15041P (DUPILUMAB) 945
15042Q (DUPILUMAB) 432
15043R (DUPILUMAB) 445
15067B (LENALIDOMIDE) 879
15073H (LENALIDOMIDE) 367
15078N (LENALIDOMIDE) 879
15079P (LENALIDOMIDE) 367
15095L (LENALIDOMIDE) 879
15096M (LENALIDOMIDE) 367
15103X (LENALIDOMIDE) 367
15104Y (LENALIDOMIDE) 879
15105B (LENALIDOMIDE) 367
15106C (LENALIDOMIDE) 879
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15113K (OCRELIZUMAB) 295
15117P (PEGCETACOPLAN) 330
15120T (OCRELIZUMAB) 807
15127E (PEGCETACOPLAN) 842
15132K (APOMORPHINE) 408
15138R (ADALIMUMAB) 656
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15140W (ADALIMUMAB) 144
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15142Y (ADALIMUMAB) 144
15143B (ADALIMUMAB) 660
15154N (ADALIMUMAB) 146
15156Q (ADALIMUMAB) 660
15173N (ADALIMUMAB) 148
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15176R (UBLITUXIMAB) 808
15177T (ADALIMUMAB) 658
15178W (ADALIMUMAB) 146
15187H (UBLITUXIMAB) 296
15197W (UBLITUXIMAB) 296
15202D (ADALIMUMAB) 148
15204F (VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR) 523
15205G (VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR) 1043
15211N (VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR) 523
15216W (VANZACAFTOR + TEZACAFTOR + DEUTIVACAFTOR) 1043
15225H (RAVULIZUMAB) 845
15231P (TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ) 1067
15234T (RAVULIZUMAB) 333
15235W (RAVULIZUMAB) 345
15244H (RAVULIZUMAB) 845
15245J (RAVULIZUMAB) 849
15246K (RAVULIZUMAB) 857
15254W (RAVULIZUMAB) 333
15255X (RAVULIZUMAB) 857
15258C (RAVULIZUMAB) 849

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