Opioid dependence treatment medicines frequently asked questions

This factsheet clarifies detailed questions regarding opioid dependence treatment (ODT) medicines reform not addressed elsewhere in the factsheets available online on the PBS website.

Prescriptions

Can patients who receive ODT medicines at multiple pharmacies access ODT medicines under the PBS?

Yes, patients who receive ODT medicines at multiple pharmacies can access their ODT medicines under the PBS. The ODT Community Pharmacy Program Rules do not prevent staged supply fees from being claimed from more than one-site.

Importantly, a prescriber cannot write more than one PBS prescription for the same pharmaceutical benefit for the same person on the same day.

It is important for prescribers and dosing pharmacists to work with patients to ensure the patient's treatment needs are met and give consideration to the most appropriate clinical care, acknowledging that in some circumstances takeaway doses or medicines such as long-acting injectable buprenorphine may not be suitable.

Under the PBS, early supply of repeats can occur where necessary under regulation 49 (previously regulation 24), and can occur at different pharmacies, however prescriptions for ODT medicines are also subject to individual state and territory regulations (which may limit this).

State and territory governments should be contacted for advice regarding respective jurisdictional policies about dosing at multiple pharmacies.

What happens if my patient requires a temporary transfer arrangement exceeding 28 days?

Prescribers can annotate a PBS ODT medicine prescription as a Regulation 49 (previously Regulation 24) prescription. Regulation 49 provides that in certain circumstances, the quantity of the original and repeats of a medicine can be supplied at the same time.

Please visit the PBS website for further information on Regulation 49 PBS prescriptions.

However, prescribers and pharmacists are reminded that relevant state and territory legislation, guidelines, and policies for ODT medicines continue to apply. States and territory governments should continue to be contacted for advice regarding arrangements for patients who require a temporary transfer arrangement exceeding 28 days.

Does a new Authority Required PBS prescription for the same strength and product cancel out existing repeats from a previous PBS prescription?

No, however the Safety Net early supply rule may apply if the patient had a script dispensed within 20 days prior for the same medicine and strength.

The Safety Net early supply rule applies to pharmaceutical benefits if the prescription is supplied within 20 days of a previous supply, usually for a month's quantity of the same medicine or any brand of an equivalent medicine to the same person under 'immediate supply' provisions.

Can Staged Supply claims be made at both pharmacies for the relevant days of the temporary transfer arrangement?

Yes, if the medicine is supplied under the PBS then registered service providers participating in the ODT Community Pharmacy Program will be able to claim a daily fee per patient for activities associated with the staged supply of eligible ODT medicines.

What happens if my patient misses a dose, or the dose is changed?

Under the PBS, patients are supplied with a quantity of ODT medicines (sometimes referred to as an allocation) and prescriptions are not valid for a specific period other than being valid for 12 months from the date written, unless applicable state or territory legislation expresses otherwise.

Prescriptions for ODT medicines are not dispensed in full to the patient. As such, clinical aspects relating to ODT medicine dosing, such as changes to a patients' dose or missed doses, can continue to be provided from the patient's allocation until the allocation is exhausted and a new prescription is dispensed.

Appropriate communication of clinical changes from prescriber to pharmacist is encouraged so the appropriate daily doses can be supplied.

In line with the ODT Community Pharmacy Program Rules, where a dose has been prepared but has not been collected by a patient, this dose can still be recorded and claimed as an in-store or take-away dosing day.

For stock management, refer to the dispensing workflow and stock management factsheet on the PBS website.

Why are PBS ODT medicines required to be dispensed in quantities of 28 days with 5 repeats, when 6 months can exceed 180 days?

Buprenorphine-containing tablets and films are available in pack sizes suitable for 28 days (i.e., tablets come in boxes of 7, films in boxes of 28). Methadone is aligned with this for consistency with other ODT medicines.

Maximum quantities for ODT medicines are equivalent to 28 days of the maximum dose per day in line with national guidelines, which is 150mg for methadone and 32mg for buprenorphine and buprenorphine with naloxone preparations.

Can prescriptions be prescribed for 6 months' supply?

The maximum quantities and repeats for ODT medicines are a recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC).

Maximum quantities for ODT medicines are equivalent to 28 days of the maximum dose per day in line with national guidelines[1] (refer Table 1 below).

Prescriptions for ODT medicines require a Streamlined Authority Code up to the maximum quantity.

Approval for increased quantities may be sought through Services Australia for methadone and buprenorphine containing sublingual tablets and film. **Prescribers can request approval for increased quantities through Services Australia either by calling telephone number 1800 888 333 or applying online.**

From 1 July 2024, up to 5 repeats can be prescribed for ODT medicines (that is, up to 6 months total supply when including the original).

Some patients require different strengths of buprenorphine-containing sublingual tablets and film to make up their daily dose. A separate PBS prescription is required for each strength.

Table 1. Maximum quantities of ODT medicines

Pharmaceutical Benefit	Brands available	Maximum Quantity	Packs
Methadone hydrochloride 5 mg/mL oral liquid 1L	Aspen Methadone Syrup ® Biodone Forte ®	840 mL	0.84 bottles
Methadone hydrochloride 5 mg/mL oral liquid 200 mL	Aspen Methadone Syrup ® Biodone Forte ®	840 mL	4.2 bottles
Buprenorphine 2 mg + naloxone 500 microgram sublingual film	Suboxone ®	84	3 packs
Buprenorphine 8 mg + naloxone 2 mg sublingual film	Suboxone ®	112	4 packs
Buprenorphine 0.4 mg sublingual tablet	Subutex ®	28	4 packs
Buprenorphine 2 mg sublingual tablet	Subutex ®	84	12 packs
Buprenorphine 8 mg sublingual tablet	Subutex ®	112	16 packs
Buprenorphine modified release injection, 8 mg, 24 mg, or 32 mg syringe	Buvidal Weekly ®	4	1 injection per pack x4
Buprenorphine modified release injection, 16 mg, 64 mg, 96 mg 128 mg or 160 mg syringe	Buvidal Monthly ®	1	1 injection per pack

[1] National guidelines for Medication-Assisted Treatment of Opioid Dependence 2014. Available at: www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence

Pharmaceutical Benefit	Brands available	Maximum Quantity	Packs
Buprenorphine modified release injection, 100 mg or 300 mg syringe	Sublocade ®	1	1 injection per pack

Can nurse practitioners continue to prescribe ODT medicines on the PBS?

Yes, nurse practitioners can continue to prescribe PBS-subsidised ODT medicines. From 1 November 2024, the Shared Care Model (SCM) administrative requirements for nurse practitioners were removed. For more information see the Review of PBS items for prescribing by nurse practitioners and endorsed midwives.

Information for applying for a prescriber number is available on the Services Australia website.

Are Section 100 programs eligible for the Closing the Gap (CTG) co-payment measure?

On 1 July 2024 the CTG co-payment measure expanded to include Section 100 medicines dispensed by community pharmacies, approved medical practitioners and private hospitals. This includes section 100 PBS medicines supplied under Continued Dispensing arrangements.

On 1 January 2025, the CTG Program further expanded to apply to all PBS medicines (i.e., including all section 85 and section 100 medicines) dispensed by public hospitals.

Note: For public hospitals in NSW or the ACT, this only applies for those hospitals currently approved under section 94 of the *National Health Act 1953* to supply PBS medicines under the Highly Specialised Drugs Program and trastuzumab under the Efficient Funding of Chemotherapy Program.

More information about the CTG Program is available here.

Can a prescription written in the community be dispensed in a hospital?

PBS ODT prescriptions written by a prescriber in a community setting can be dispensed by any PBS approved supplier, including section 94 (public or private) hospitals.

Prescriptions for medicines listed under PBS Section 100 HSD (Community Access) arrangements, like ODT medicines, can be dispensed by any PBS approved supplier able to dispense HSD medicines.

Prescribers are reminded to follow state and territory legislation when writing ODT medicine prescriptions.

Can prescribers write non-PBS prescriptions post 1 July 2023?

Yes, ODT medicines can still be prescribed and dispensed privately. However, prescriptions written after 1 July 2023 must be written as PBS prescriptions in order to be dispensed and claimed on the PBS.

If a prescription written after 1 July 2023 does not meet PBS requirements, pharmacists should contact the prescriber for a new PBS prescription as they would for other PBS medicines.

Dispensing

Is the Commonwealth continuing to pay for the cost of ODT medicines?

The Commonwealth subsidises the cost of medicines through the PBS.

In line with usual PBS arrangements, the pharmacy orders medicines through their pharmaceutical wholesaler/manufacturer subject to wholesaler/manufacturer trading terms.

PBS approved suppliers receive reimbursement from the Commonwealth through claims for payment which are submitted to Services Australia.

Section 90 community pharmacies can receive the following remuneration for HSD medicines:

- the cost of the medicine (approved ex-manufacturer price)
- PBS fees (dispensing fee, HSD mark up and dangerous drug fee).

In addition, section 90 community pharmacies can also claim the ODT Community Pharmacy Program staged supply and buprenorphine injection fee through the Pharmacy Programs Administrator (PPA).

Do I need to label the full PBS quantity for my patient and store separately?

No, as long as pharmacists have a method of keeping track of a patient's PBS quantity (there are a variety of ways to do this), the full amount does not need to be packaged.

Is dose management software being updated to include PBS dispensing?

There are currently three vendors of dose management software integrated with the PPA portal to allow for direct claims of ODT medicines dispensed under the PBS Section 100 HSD Program through the software.

Service Providers not utilising the integrated dose management software will need to claim directly via the PPA portal.

How do I keep track of a patient's PBS supply for claiming the Staged Supply fee under the ODT Community Pharmacy Program?

For pharmacies that do not have dose management software, an 'ODT Staged Supply Temporary Data Capture Form' is available on the PPA website.

Can buprenorphine injections be dispensed early?

Similar to other PBS medicines, patients are able to receive early supply of ODT medicines if necessary. If the minimum interval of 20 days has passed since the previous supply, the PBS co-payment amount will contribute to the patient's PBS Safety Net threshold.

Repeat intervals are required in some states and territories – please consult the regulations in your jurisdiction.

Importantly, buprenorphine injections **cannot** be supplied directly to the patient and instead must be supplied to a person approved to administer the injection to the patient.

What do I do if my patient does not have a Medicare card?

Patients must have a Medicare card to access PBS subsidised ODT medicines.

There are some exceptional situations in which a Medicare special number can be used for an eligible patient who cannot present their own Medicare number on the day. This includes emergency situations or if the patient is an eligible overseas visitor. Temporary residents who hold a current visa may be able to access Medicare if they meet certain criteria.

Please note, eligible patients can apply for their own Medicare card online by enrolling in Medicare on the Services Australia website.

Usually, patients who are not eligible for the PBS subsidy will either access their medicines privately or through state and territory services. Prescribers and pharmacists may wish to liaise with state and territory governments regarding ongoing ODT access for patients who are not Medicare eligible and who are unable to access ODT medicines privately.

Do ODT medicines receive a wholesale mark-up under the HSD Program?

From 1 July 2026, eligible Section 100 HSD medicines (including ODT medicines) supplied by community pharmacies are included under the First Pharmaceutical Wholesaler Agreement (1PWA), which introduces a new wholesaler mark-up structure. Further information is available in the First Pharmaceutical Wholesaler Agreement fact sheet.

Are PBS fees indexed?

The PBS ready-prepared dispensing fee and dangerous drug fee are indexed annually on 1 July each year.

Fees for the ODT Community Pharmacy Program can be considered in the context of the next Community Pharmacy Agreement in line with other Community Pharmacy Programs.

Can I charge delivery fees under the PBS?

Under the PBS, an approved PBS supplier may make a special charge equal to the cost of delivery for delivery of a pharmaceutical benefit to a place other than the premises of which an approved pharmacist is approved.

Can I charge a patient additional administration fees when supplying ODT medicines on the PBS?

Under the PBS, patients pay the PBS co-payment and no additional private dosing or dispensing fees can be charged.

Section 90 approved community pharmacies can claim ODT Community Pharmacy Program Staged Supply and Buprenorphine Injection Administration fees for ODT medicines dispensed under the Section 100 Highly Specialised Drugs (HSD) Program.

What do I do if there is a medicine shortage for an ODT medicine?

Information about medicine shortages, including current shortages, is available on the Therapeutic Goods Administration (TGA) Shortages website.

Wholesalers may experience an increase in demand for ODT products during particular periods.

Please note, there are two brands of methadone oral liquid available (Aspen Methadone Syrup® and Biodone Forte®).

Are ODT medicines supplied under Community Service Obligation arrangements?

As with other Section 100 medicines, ODT medicines are not part of the Community Services Obligation Funding Pool (CSO) arrangements.

CSO distributors are not required to supply PBS Section 100 medicines to community pharmacies at or below CSO price, including non-dual listed items or dual listed items.

Note: CSO arrangements extend only to section 90 community pharmacies.

Do ODT medicines still need to be stored in line with state and territory regulations?

Yes, state and territory policies, guidelines, and regulations should continue to be observed when handling and storing ODT medicines.

How do I manage the PBS stock for a patient?

Refer to the dispensing workflow and stock management factsheet on the PBS website.

ODT Community Pharmacy Program

Can I claim for other Staged Supply medicines as well as ODT medicines?

Section 90 PBS approved community pharmacies can claim different services for the same patient in line with the Program Rules for each Community Pharmacy Program.

Information regarding Community Pharmacy Programs is available on the PPA website.

Can hospitals submit claims for the ODT Community Pharmacy Program?

The ODT Community Pharmacy Program is available to section 90 PBS approved community pharmacies only, who are authorised by their relevant state or territory to supply ODT medicines. Hospital pharmacies are not eligible to claim fees under the ODT Community Pharmacy Program.

Details for ODT Community Pharmacy Program eligibility is available in the Program Rules on the PPA website.

Can prescribers claim the injection fee under the ODT Community Pharmacy Program?

The ODT Community Pharmacy Program is only available to section 90 community pharmacies.

Prescribers can continue to treat and provide clinical services, including administration of buprenorphine injections, to patients which include services rebated under the Medicare Benefits Schedule.

Do all my patients need to sign the PPA consent form for the ODT Community Pharmacy Program?

Community pharmacies are required to obtain written consent from the patient (or carer) prior to providing services under the ODT Community Pharmacy Program.

The consent relates to patient access to the program, reporting, and claiming. Further information about collected information, including the information statement and consent form is available from the PPA website.

Patients

Will ODT medicines be visible in My Health Record? Can I change this?

Dispensing of ODT medicines on the PBS will appear in My Health Record (MHR). This is a change to previous practice, as ODT medicines were previously dispensed as a private prescription.

MHR is a consumer-controlled system. MHR is a safe and secure system, and patients are in control of it. Patients can manage their important information, control who has access to it, and see what has been accessed.

Patients can choose to restrict access to your record or to specific documents.

- You can decide which of your healthcare providers can access your record by setting a record access code.
- You can set particular records to Restricted Access, meaning a health professional will need an access code to access that record.

Once patients log into their My Health Record, select the 'Privacy and Access' tab from the home bar. Patients can then select either:

1. ‘My Healthcare Organisations’ and set an access code for health professionals which you will need to provide them to access your MHR.
2. ‘Manage My Document Access’ and select the documents you wish to restrict access to and then set an access code for health professionals which you will need to provide them to access your MHR.

General

Can I continue prescribing and/or dispensing ODT medicines privately?

Yes. Patients can choose not to have their ODT medicines dispensed on the PBS, and instead choose a private prescription, However, if a patient opts for a private prescription, the patient will likely be charged privately for the cost of the medicine as well as any outgoing daily dosing fees (and would not be charged the PBS co-payment). These charges are not regulated and can vary between pharmacies.

Amounts paid by patients for private prescriptions do not count towards their PBS Safety Net threshold.

In addition, as the pharmacy would be dispensing privately, pharmacies are not eligible to claim the ODT Community Pharmacy Program Staged Supply or Buprenorphine Injection Administration fees through the PPA Portal.

How can I provide opportunistic dosing for my patients from my practice?

Longer-term, medical practices and clinics should liaise with PBS pharmacies as to the most suitable arrangements to support PBS dispensing and provision of opportunistic dosing.

Can private clinics continue to charge private dosing fees?

Yes. Under the PBS, private clinics or non-PBS dosing sites are not prevented from charging private dosing fees to patients, even if supplies of ODT medicines are made under the PBS (with the private clinic acting as an agent).

While PBS approved suppliers are limited by the *National Health Act 1953* in the charges they can seek from patients, this does not extend to private clinics.

Patients who choose to access ODT medicines through a private clinic may be asked to pay the PBS co-payment and additional private dosing fees.

Can GPs become section 92 dispensing medical practitioners for injectable buprenorphine?

Under section 92 of the *National Health Act 1953* approval may be granted to a medical practitioner to supply PBS medicines in a particular area, typically remote or isolated, where

the community does not have convenient and efficient access to PBS medicines supplied by an approved community pharmacy in that area or surrounding locality.

The medical practitioner must:

- be practising medicine in the area for which approval is being sought
- hold a current registration with the relevant state or territory medical board
- be willing to supply PBS medicines to any person in that area who presents a valid PBS prescription.

Information for applying to become a PBS approved supplier is available on the Department of Health and Aged Care website.

How can public hospital inpatients access ODT medicines?

The Australian Government provides the states and territories funding through the National Health Reform Agreement for public hospital services.

This means state and territory governments manage access to medicines for inpatients of public hospitals, including ODT medicines outside the PBS. The management of these medicines may vary between jurisdictions.

Will the changes mean there will be PBS data for ODT medicines in the same way there is for other PBS medicines?

Yes, data relating to the PBS is captured by Services Australia as part of the PBS claim for payment.

Who can I call if I have trouble prescribing or dispensing ODT PBS prescriptions?

Prescribers, pharmacists, and patients can contact the Services Australia PBS general enquires line 132 290 or the Medicare general enquiries line 132 011 which are open 24 hours, 7 days.

State and territory governments remain the first point of contact regarding the operation of ODT programs in their respective jurisdictions.

State	Helpline/organisation	Contact	Availability
ACT	Alcohol and Drug Service Intake & Helpline	(02) 5124 9977	8:00am to 5:00pm Monday, Tuesday, Thursday, and Friday
NSW	Opioid Treatment Line	1800 642 428	9:30am to 5:00pm Monday to Friday
NSW	Pharmaceutical Services	(02) 9424 5921 or 9391 9944 (Select option 4)	8:30am to 5:00pm Monday to Friday
NT	Top End Alcohol and other Drug Services	08 8922 8399	-

NT	Alcohol and other Drugs Services Central Australia (ADSCA)	08 8951 7580	
QLD	Queensland Opioid Treatment Program	QOTP@health.qld.gov.au	-
QLD	Alcohol and Drug Information Service (including the Alcohol and Drug Clinical Advisory Service)	1800 177 833	24 hours, 7 days
SA	Alcohol and Drug Information Service	1300 131 340 (08) 7087 1743 for interstate callers	8:30am to 10:00 pm 7 days
TAS	Alcohol and Drug Service (appointments or info)	1300 139 641	9:00am to 5:00pm Monday to Friday
TAS	Alcohol and Drug Information Service	1800 250 015	24 hours, 7 days, free call
WA	Community Pharmacotherapy Program	(08) 9219 1907	8:30am to 4:30pm Monday to Friday
WA	Alcohol and Drug Support Service	(08) 9442 5000 or toll free 1800 198 024	24 hours, 7 days
WA	Next Step Drug and Alcohol Services	(08) 9219 1919	-
VIC	Drug and Alcohol Clinical Advisory Service (DACAS)	1800 812 804	24 hours, 7 days
VIC	DirectLine	1800 888 236	24 hours, 7 days
VIC	Pharmacotherapy advocacy, mediation and support (PAMS) service	1800 443 844	-

VIC	Victorian Opioid Pharmacotherapy Program	pharmacotherapy@health.vic.gov.au	-