



Opioid dependence treatment medicines - dispensing workflow and stock management

This factsheet provides information for pharmacists for dispensing and stock management of opioid dependence treatment (ODT) medicines from 1 July 2023.

PBS ODT medicine prescriptions

1. A prescription written after 1 July 2023 must meet PBS requirements. to be dispensed and claimed on the PBS.
2. Obtain written consent from the patient for provision/administration of ODT Community Pharmacy Program services and provision of patient data to the Pharmacy Programs Administrator (PPA)/the Department of Health and Aged Care (the department). The form is available [here](#) and at [Appendix A](#).
3. Dispense the prescription via your dispensing software:
 - If a patient is on multiple strengths of buprenorphine, you will dispense multiple scripts, e.g. Dispense Suboxone® 2 mg and Suboxone® 8 mg for a patient currently on 10 mg buprenorphine films daily.
 - The prescription must meet the PBS requirements.
 - Maximum quantity:
 - Streamlined authority: equivalent to 28 days of the maximum dose per day in line with national guidelines¹ which is 150 mg for methadone and 32 mg for sublingual buprenorphine and buprenorphine with naloxone.
 - Telephone (or online) authority approval: required for increased quantities of oral or sublingual ODT formulations.
 - Prescriptions will have up to a maximum of 5 repeats.
 - The prescriber may provide additional clinical instructions separate to the PBS prescription, for example takeaway entitlements.
4. Store the original and repeats in the patient's file. Repeats should not be given to the patient.
5. The patient pays a PBS co-payment for each prescription dispensed - \$7.70 for concessional patients or up to \$25.00 for general patients.
 - **You cannot charge the patient any other fees.**
6. For clients who visit other pharmacies for other PBS medicines, complete the [Safety Net prescription record form](#) for the patient.

Recording supply of ODT medicines

The below outlines the steps to be taken to record supply of ODT medicines to meet the requirements of the ODT Community Pharmacy Program and is dependent on which software, if any, is used in the pharmacy to manage ODT dosing.

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

Pharmacists are reminded to ensure any recording of supply of schedule 8 drugs of addiction also meets relevant state or territory legislative requirements.

Electronic register

Please contact your software vendor for step-by-step instructions.

Paper register

1. Record the amount supplied to the patient on that day in the schedule 8/drugs of addiction book in accordance with state/territory requirements and in accordance with pharmacy protocols.
 - Do not record the maximum quantity of the PBS prescription as one entry.
2. Complete the [ODT Staged Supply Service Temporary Data Capture Form](#) or the [In-Pharmacy Administration of ODT Injection Service Temporary Data Capture Form](#) for each patient each time a medicine is administered/supplied.
 - It is recommended that the client's daily dose is prominently displayed on the ODT Staged Supply Temporary Data Capture Form to assist with confirmation of dose each day.
3. Store the data capture form in the patient's file or in accordance with pharmacy protocols.

Claiming payment (ODT Community Pharmacy Program)

All claims must be submitted via the PPA portal on a monthly basis in arrears (e.g., services provided in November must be claimed by 31 December).

There are no limits to how many patients can be claimed for each month via the PPA Portal.

For oral or sublingual ODT medicines

Service Providers (section 90 community pharmacies) must submit eligible ODT Staged Supply Service claims via the PPA Portal on a monthly basis per eligible patient in arrears.

Electronic register

Please contact your software vendor for step-by-step instructions to submit electronic claims to the PPA portal.

Paper register

1. Submit an ODT Staged Supply Claim via the [PPA portal](#) for each patient at the end of the month.
2. Retain the hard copy record of the [ODT Staged Supply Service Temporary Data Capture Form](#) for each patient for 7 years.

For injectable ODT medicines

Service Providers (section 90 community pharmacies) must submit eligible ODT Injection (long-acting injectable buprenorphine) claims via the PPA Portal. Each injection must be submitted as a separate claim and can be submitted as soon as the injection has been administered if the pharmacy chooses to do so.

Note: unlike the ODT Staged Supply Service claims, there is no need to wait until the calendar month has ended to submit an ODT Injection claim.

Electronic register

Please contact your software vendor for step-by-step instructions to submit electronic claims to the PPA portal.

Paper register

1. Submit an ODT Injection Claim via the [PPA portal](#) for each patient each time an injection is administered in the pharmacy, once the portal is operational.
2. Retain the hard copy record of the [In-Pharmacy Administration of ODT Injection Service Temporary Data Capture Form](#) for each administration for 7 years.

Stock management

The Commonwealth does not intend to audit pharmacies with respect to the amount of medicine provided to the patient in daily/take-away doses compared to the amount prescribed for the maximum quantity, acknowledging there can be clinical reasons why the dosing schedule may be varied by the prescriber or other events such as missed or spilled doses which would render such an audit impractical. However, pharmacies are advised to keep records of any changes in dosing (as is current practice) that may result in a patient receiving less than the PBS prescribed quantity.

The provision of ODT medicines under the PBS is intended to operate in parallel with jurisdictional ODT programs. Pharmacists should ensure that they are practicing in accordance with their state or territory legislative requirements.

Pharmacists should in all circumstances use professional judgement to determine appropriate action with regard to the remaining balance of medicines with consideration of the circumstances of discontinuation, legal requirements and duty of care.

The below details the policy from the Commonwealth/PBS perspective at a principles level without going into all possible scenarios.

Discontinuation of program	Once dispensed, the staged supply of ODT medicines may be discontinued by the prescriber, pharmacist or the patient. The Commonwealth considers that any remaining quantities of medicine in the patient's allocation (i.e., the balance of the maximum quantity dispensed on the S100 HSD PBS prescription and the quantity supplied to the patient prior to the discontinuation) should be returned to available stock and will no longer be available for the patient to access. This is in keeping with relevant national guidelines and supports the safe use of medicines.
Management of missed doses	The quantity prescribed for a patient is intended to be sufficient for 28 days' supply plus up to five repeats. However, in an instance where, for example, a dose is missed the next prescription should not be dispensed until any remaining quantity has been expended, provided the prescriber has not issued any variations to the drug/other changes that would warrant a new prescription. If a dose has already been prepared and is missed the pharmacist should use professional judgement to determine if the medicine should be returned to available stock or destroyed in accordance with professional practice standards and legal requirements for Schedule 8 medicines.
New prescription with doses remaining	When a new prescription is written by the treating health professional with the intention that it supersedes any existing prescription, any remaining quantities on the previous prescription should be returned to pharmacy stock.
Management of variation in dosing	The maximum quantity prescribed can be provided to the patient in accordance with any phone or written orders by the treating health professional. For example, if a temporary increase to the dose is ordered, in accordance with any state and territory requirements, and there is sufficient quantity on the existing prescription this can be managed within the available quantity.

Appendix A

OPIOID DEPENDENCE TREATMENT (ODT) COMMUNITY PHARMACY PROGRAM – PATIENT INFORMATION STATEMENT AND CONSENT FORM

INFORMATION STATEMENT

1. You have been prescribed one or more opioid dependence treatment medicines that are available on the Pharmaceutical Benefits Scheme (PBS), for dispensing at your community pharmacy.

Under this program, opioid medicines that are listed on the Section 100 Highly Specialised Drugs Program (Community Access) will be dispensed by your pharmacy under the PBS. This means you will need to pay a PBS co-payment towards your medicine (this amount varies depending on whether you hold a concession card and/or if you have reached the PBS Safety Net threshold) and the amount you pay will count towards your PBS Safety Net record.

The Australian Government will pay your pharmacy for the staged supply provision/administration of your ODT Community Pharmacy Service medicines.

Any additional patient fees are not permitted under this program, so the most you should pay is the general or concessional PBS co-payment amount for the medicine itself.

In order to receive this service, you need to:

- Have a valid Medicare and/or Department of Veterans' Affairs (DVA) card
- Have been enrolled in a state or territory ODT program and receiving ODT medicines from your community pharmacy.

Under this service your pharmacist will:

- Assess your eligibility to receive the service
- Obtain informed consent from you to receive the service
- Collect personal and sensitive information from you to enable the pharmacy to claim a payment for delivery of this service
- Provide these PBS medicines to you in instalments (i.e. dosing in the pharmacy or take-aways), or as an injection.

Australian Privacy Principle 5 Notification under the *Privacy Act 1988*

Your personal information is protected by law, including the *Privacy Act 1988*.

Collection of personal information to allow payment to your pharmacist

The Department and the Pharmacy Programs Administrator are collecting your personal information to verify your eligibility to receive ODT Community Pharmacy Services and enable the pharmacy to claim a payment for the delivery of the service to you.

Personal information, such as your Medicare/DVA number and the medications you are taking will be collected by your pharmacist and disclosed for this purpose.

If you consent to receive these funded services by completing and signing the consent form, your personal information will be collected for this purpose.

Further Information

The Department is unlikely to disclose your personal information to overseas recipients.

The Department can be contacted by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at www.health.gov.au.

The Pharmacy Programs Administrator can be contacted by telephone on 1800 951 285 or email at support@ppaonline.com.au.

The Department has a privacy policy which you can read at <https://www.health.gov.au/resources/publications/privacy-policy>

The Pharmacy Programs Administrator has a privacy policy which you can read at www.ppaonline.com.au/privacy-policy.

You can obtain copies of these privacy policies by using the contact details set out above. The privacy policies contain information about:

- How you may access the personal information the Department or Pharmacy Programs Administrator holds about you and how you can seek correction of it
- How you may complain about a breach of the Australian Privacy Principles and how complaints are dealt with.

ACKNOWLEDGEMENT

I have been provided (verbally or in writing), the contents of the ODT Community Pharmacy Program Information Statement and understand the services and what I am consenting to.

CONSENT

I consent to receive ODT Community Pharmacy Services and in doing so I consent to the collection of my personal information by the Pharmacy Programs Administrator and the Australian Government Department of Health and Aged Care and to enable the pharmacy to claim a payment for delivery of that service.

Signature		Date	
Print name			

If you are signing on behalf of the Participant, please indicate your relationship to the Participant:

- Parent or guardian of child
- Other – Please tick applicable category below:
 - Enduring Guardian, recognised by a relevant State or Territory law
 - Enduring Power of Attorney, recognised by a relevant State or Territory law
 - A person recognised by a relevant State or Territory law
 - A person who has been nominated in writing by the Participant while the Participant was capable of giving consent.

This program is funded by the Australian Government.

 **CONTACT THE SUPPORT CENTRE:** 1800 951 285 |support@ppaonline.com.au