



Opioid dependence treatment medicines - Information for community and hospital pharmacists

Overview

Nationally consistent payment arrangements for opioid dependence treatment (ODT) services delivered through community pharmacies

On 1 July 2023, a new ODT Community Pharmacy Program was established and is administered by the [Pharmacy Programs Administrator \(PPA\)](#). This Program is supported through funding of \$377.3 million over 4 years from 2023-24 as announced in the Federal budget. There is also an allocation of \$98.4 million per year in ongoing funding.

The ODT reforms mean less out-of-pocket costs for patients accessing treatment within the community pharmacy sector by supporting the delivery of ODT pharmacy services.

Supplying patients with methadone liquid, buprenorphine sublingual tablets and buprenorphine + naloxone sublingual films often require frequent in-pharmacy and take-away dosing activities. The ODT Community Pharmacy Program introduced nationally consistent payment arrangements for ODT staged supply services provided by section 90 approved community pharmacies. Subject to their respective state and territory policies and regulations, section 90 approved community pharmacies can also receive a fee for on-site pharmacist administration of injectable buprenorphine.

The ODT Community Pharmacy Program complements, but is not part of, PBS arrangements for the supply of ODT medicines. For further information about the Program, refer to the Program Rules available from the [PPA website](#).

The way in which ODT medicines are listed on the PBS Schedule has changed

On 1 July 2023, [ODT medicines](#)¹ became part of the [Section 100 Highly Specialised Drugs \(HSD\) Program \(Community Access\) arrangements](#) and the claiming of prescriptions is administered by Services Australia. This means the way ODT medicines are prescribed, ordered, supplied (dispensed) and remunerated is just like other PBS medicines under the Section 100 HSD Program (Community Access).

The inclusion of ODT medicines under the Section 100 HSD Program is intended to address the core issues of patient affordability and equitable access to ODT medicines through the PBS, such that access to PBS subsidised ODT medicines aligns with usual PBS arrangements including the PBS co-payment and safety net arrangements.

The [National Health \(Highly specialised drugs program\) Special Arrangement 2021](#) provides the legislative framework for the Section 100 HSD Program.

¹ ODT medicines currently listed on the PBS include methadone oral liquid, buprenorphine sublingual tablets, buprenorphine with naloxone sublingual films and long-acting injectable buprenorphine products.

State and Territory Opioid Dependence Treatment Programs

State and territory governments operate individual ODT programs in their respective jurisdictions. These programs include patient eligibility criteria, take-away dosing policies, as well as the approval or authorisation of participating prescribers (medical practitioners and nurse practitioners) and dispensing (dosing) points.

The operation of state and territory ODT programs continue to be governed by the respective policies, guidelines and regulations within each of those jurisdictions. The provision of PBS subsidised access to ODT medicines operates in parallel with jurisdictional ODT programs.

ODT medicines are listed as controlled drugs in Schedule 8 of the [Poisons Standard](#), and therefore have specific requirements for handling, storage, prescribing and dispensing which are given effect through the relevant state and territory legislation.

Suppliers such as pharmacies must also comply with the provisions of state and territory regulations for controlled drugs when dispensing medicines for the treatment of opioid dependence under the PBS.

Section 100 HSD Program community access arrangements

Patient charges

As of 1 July 2023, patients must be charged consistently with general PBS arrangements.

Under the Section 100 HSD Program, PBS-eligible patients pay the [PBS co-payment](#) for the supply of their ODT medicines (usually for up to 28 days' supply per pharmaceutical benefit prescribed) and the amount paid will contribute towards the patient's PBS Safety Net threshold.

Buprenorphine-containing ODT medicines is prescribed and dispensed on a per-pack basis, like the prescribing of other PBS medicines (also refer to Supply of ODT medicines below). This means if different strengths are prescribed and supplied, each strength will attract one PBS co-payment and relevant PBS remuneration.

PBS approved suppliers cannot charge patients additional private dispensing or dosing fees for the supply of their ODT medicine under the PBS. Pharmacies should treat under co-payment prescriptions for ODT medicines in the same way as all [under co-payment](#) medicines supplied under the PBS.

Refer [Fees, Patient Contributions and Safety Net Thresholds](#) on the PBS website.

Supply of ODT medicines

ODT medicines listed under the Section 100 HSD Program can be dispensed from a:

- section 90 approved community pharmacy
- section 94 public hospital pharmacy
- section 94 private hospital
- section 92 dispensing doctor (e.g., in remote areas without an approved pharmacy)

Patients must have a Medicare card to access PBS subsidised ODT medicines. With patient consent, pharmacists may (at their discretion) keep a record of a patient's Medicare number so the patient does not have to show the actual card every time a prescription is lodged.

Eligible patients can apply for their own Medicare card online by enrolling in Medicare on the Services Australia [website](#). Temporary residents who hold a current visa may be able to

access Medicare if they meet certain criteria. This is outlined on the Services Australia [website](#).

Similar to other PBS medicines, patients will be able to receive [early supply](#) of ODT medicines in some circumstances. If the minimum interval of 20 days has passed since the previous supply, the PBS co-payment amount will contribute to the patient's Safety Net threshold.

Ordering ODT medicines

As of 1 July 2023, PBS approved suppliers, such as approved pharmacists, purchase stock of ODT medicines from their usual pharmaceutical distributor/wholesaler and submit claims for Commonwealth payment to Services Australia for supply of ODT medicines.

Storage and handling of ODT medicines

Medicines for the treatment of opioid dependence are frequently given to patients without traditional packaging of a full PBS quantity, for example a daily dose of liquid methadone or buprenorphine-containing tablets or films.

Under the PBS, it may be impractical for approved pharmacists to label and store the full dispensed PBS quantity for each patient in these circumstances. Therefore, pharmacists and other approved suppliers can continue to share a bottle of methadone between multiple patients in the process of administering a particular patient their full PBS supply over the month.

For example, methadone liquid is prescribed and dispensed on a maximum millilitre (mL) basis per prescription (that is, a total quantity in mL for up to 28 days of the daily dose amount). However, a patient's daily dose may be prepared from a shared 1 L bottle.

Pharmacists must continue to manage the storage, handling, and recordkeeping of ODT medicines in line with state and territory regulations for controlled drugs.

Payment arrangements

Section 90 approved community pharmacies should refer to the Factsheet: Opioid dependence treatment medicines – claiming and payment arrangements for community pharmacies for information about fees under the PBS and the ODT Community Pharmacy Program.

As part of the PBS claim, pharmacists are remunerated for the ex-manufacturer price of the drug dispensed. In addition, the remuneration rates for HSDs (including ODT medicines) supplied through PBS approved community pharmacies and approved private hospital pharmacies is the normal PBS ready-prepared dispensing fee, the dangerous drug fee (indexed annually, see [Pharmaceutical Benefits Scheme \(PBS\) | Fees & Patient Contributions](#)), plus a Section 100 mark-up ascertained as follows:

- 10% for drugs with an ex-manufacturer price of less than \$40
- \$4 for drugs with an ex-manufacturer price of between \$40 and \$100
- 4% for drugs with an ex-manufacturer price of between \$100.01 and \$1000
- \$40 for drugs with an ex-manufacturer price of greater than \$1000

Under the Section 100 HSD Program, PBS approved public hospitals receive reimbursement for the approved ex-manufacturer price or the proportional ex-manufacturer price for each dispensed quantity (i.e., the cost of the drug).

PBS prescriptions

As of 1 July 2023, like other PBS medicines, new prescriptions that are written by eligible prescribers for ODT medicines will need to meet the PBS requirements to be dispensed.

Maximum quantities for ODT medicines are equivalent to 28 days of the maximum dose per day in line with national guidelines² which is 150 mg for methadone and 32 mg for sublingual buprenorphine and buprenorphine with naloxone.

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 oral methadone and sublingual formulations of ODT medicines in line with the Pharmaceutical Benefits Advisory Committee recommendation. Prescribers can request approval for increased quantities through Services Australia either by calling telephone number 1800 888 333 or applying [online](#).

Up to 5 repeats can be prescribed for ODT medicines (that is, 6 months total supply when including the original).

Additional clinical instructions can be provided separate to the PBS prescription (which provides a total supply quantity). In line with state and territory ODT program requirements, prescribers are encouraged to continue to provide clear daily dosing instructions including dose variations and take away arrangements to the PBS approved supplier, to support the dose administration (staged supply) of these medicines to patients.

Provided the patient does not need to be prescribed a new PBS pharmaceutical benefit (for example, a different drug or strength of drug) it is expected the prescriber and PBS approved supplier would communicate/confirm dose variations, as is currently common practice.

For prescriptions written to facilitate variable or dosing within a range, it is suggested the maximum quantity should be calculated based on the maximum daily dose required.

For more detailed information refer to the Information for Prescribers document.

² 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

