**Opioid dependence treatment medicines - Information for prescribers**

## Overview

**The way in which opioid dependence treatment (ODT) medicines are listed on the PBS Schedule has changed**

ODT medicines listed on the Schedule of Pharmaceutical Benefits (the PBS Schedule) include:

1. methadone oral liquid (Aspen Methadone Syrup ® and Biodone Forte ®)
2. buprenorphine sublingual tablets (Subutex ®)
3. buprenorphine with naloxone sublingual films (Suboxone ®)
4. long-acting injectable buprenorphine products (Buvidal ® and Sublocade ®).

On 1 July 2023, [ODT medicines](https://www.pbs.gov.au/browse/section100-md) became part of the [Section 100 Highly Specialised Drugs (HSD) Program (Community Access) arrangements](https://www.servicesaustralia.gov.au/community-access-for-highly-specialised-drugs?context=23411) and the claiming of prescriptions is administered by Services Australia.

This means ODT medicines are prescribed, ordered, supplied (dispensed) and remunerated 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*](https://www.legislation.gov.au/Series/F2021L00374)provides the legislative framework for the Section 100 HSD Program.

**What this means for ODT patients**

As of 1 July 2023, under the Section 100 HSD Program, PBS-eligible patients pay the [PBS co-payment](https://www.pbs.gov.au/info/about-the-pbs#What_are_the_current_patient_fees_and_charges) for the supply of their ODT medicines from PBS approved pharmacies (usually for up to 28 days’ supply per pharmaceutical benefit prescribed). The amount paid will contribute towards the patient’s PBS Safety Net threshold.

Buprenorphine-containing ODT medicines are prescribed and dispensed on a per-pack basis, like the prescribing of other PBS medicines. This means if different strengths are prescribed and supplied, each strength will attract one PBS co-payment.

Patients are no longer charged private daily dispensing or dosing fees by PBS approved pharmacies to access their medicines. Prescribers are encouraged to talk to patients about the changes and advise patients that they will be paying the PBS co-payment for ODT medicines[[1]](#footnote-1).

## Prescribing ODT medicines under the Section 100 HSD Program community access arrangements

As of 1 July 2023, like other PBS medicines, new prescriptions that are written by eligible prescribers (i.e., PBS eligible medical practitioners and nurse practitioners) for ODT medicines will need to meet the PBS requirements to be dispensed. Requirements for PBS prescriptions are provided by Part 5 of the [*National Health (Pharmaceutical Benefits) Regulations 2017*](https://www.legislation.gov.au/Details/F2023C00313)*.* Note: PBS stationery can be ordered through [Services Australia](https://www.servicesaustralia.gov.au/pbs-and-rpbs-stationery-for-medical-practitioners?context=22851).

**Table 1. Writing PBS Prescriptions**

|  |  |
| --- | --- |
| Prescription requirement  | Description  |
| Prescriber details  | Prescriber details must be included on the prescription. This includes the prescribers’ PBS Prescriber Number, date, and signature. |
| PBS Authority Numbers and codes  | Each prescription will need to have a PBS Authority Prescription Number that is pre-prepared on an authority prescription pad or generated through prescribing software for printed prescriptions or electronic prescriptions.Each script must also include the relevant Authority Approval code i.e., the Streamlined code for up to the maximum quantity. Prescriptions for approved authorities for increased quantities of oral and sublingual ODT medicines will have an Authority Approval Number.  |
| Patient details  | Patient’s name, residential address, Medicare details and any concession or entitlement card details.  |
| Medication and dose  | Details of the pharmaceutical benefit i.e., name of drug, form, strength. |
| Maximum quantity and repeats  | The total quantity or number of units to be supplied and the number of repeats. See Table 2 for maximum quantities. |
| Directions  | Provide clear dosing instructions including the daily dose and any dose variations applicable. Additional clinical instructions e.g. take-away dosing instructions may be supplied separate to the PBS prescription. |
| Schedule 8 requirements | Continue to follow the requirements for writing Schedule 8 (Controlled Drug) prescriptions of your state or territory. |

**Prescribing ODT medicines – maximum quantities and repeats**

Maximum quantities for ODT medicines are equivalent to 28 days of the maximum dose per day in line with national guidelines[[2]](#footnote-2) (refer Table 2 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**](http://www.servicesaustralia.gov.au/hpos?context=22786)**.**

Up to 2 repeats can be prescribed for ODT medicines (that is, 3 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 2. Maximum quantities of ODT medicines**

| **Pharmaceutical Benefit** | **Brands available** | **Maximum Quantity** | **Packs** |
| --- | --- | --- | --- |
| Methadone hydrochloride 5 mg/mL oral liquid 1L | Aspen Methadone Syrup ®Biodone ® | 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 |
| Buprenorphine modified release injection, 100 mg or 300 mg syringe | Sublocade ® | 1 | 1 injection per pack |

**Directions for patient dosing and take-aways**

It is common for patients to be on a variable dose of ODT medication. This may occur, for example, during initiation or when the patient is changing medication.

Prescribers are encouraged to prescribe only the quantities and repeats that are suitable for the patient’s clinical needs (including during medication initiation) until their next review.

Patients will continue to be dosed by their pharmacy according to the dosing schedule provided. Dosing will continue to be recorded as per current practice according to state and territory requirements.

Additional clinical instructions can be provided separate to the PBS prescription (which provides a total supply quantity for the medication). 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.

* if the patient is on a variable dose where the dose may increase according to a specific regimen, the quantity on the PBS prescription should be the sum of the variable doses each day up to 28 days
* if the patient is dosed within a range each day, the quantity on the PBS prescription should be calculated according to the maximum dose in the range per day (multiplied by up to 28 days). This will ensure the prescription covers a sufficient quantity should the patient receive the maximum dose each day
* if the patient has missed a dose/s and they are prescribed a new dose, updated clinical directions can be provided to the treating pharmacy. The quantity of medicine dispensed under the PBS prescription can continue to be used until a new PBS prescription is required.

Please communicate/confirm any dose variations with the patient’s treating pharmacy per current practice.

**Note**: a new PBS prescription will be required if the strength of the medicine changes or if a different/new ODT medication is prescribed.

Prescribing and administering long-acting injectable buprenorphine in clinics including GP practices and medical centres

Clinics can continue to offer treatment, including with long-acting injectable buprenorphine, by obtaining supplies dispensed by PBS approved pharmacies.

All existing clinics which currently treat and provide clinical services to patients, including services rebated under the Medicare Benefits Schedule, can continue to do so. \. PBS prescribers will be able to prescribe ODT medicines, but they will not be able to dispense medicines under the PBS Section 100 HSD Program. Under the *National Health Act 1953*, only approved pharmacies can dispense PBS medicines.

Transitional arrangements for supplies to authorised private clinics and non-PBS approved dosing sites

Under the ODT transitional arrangements (refer **Factsheet on Transitional Arrangements for private clinics and non-PBS approved dosing sites**), authorised private clinics and non-PBS dosing sites can continue to order long-acting injectable buprenorphine (and other ODT medicines) directly to the clinic as per current arrangements up until 30 June 2024 (extended from original end date of 30 November 2023). These transition arrangements allow state and territory governments time to work with non-PBS dosing sites to transition patients to a PBS approved community pharmacy or make other arrangements.

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| Box 1: Following the 1 July 2023 changesIn the months following 1 July 2023, prescribers should: 1. Provide patients with a new PBS paper or electronic prescription
2. Advise patients that when attending a pharmacy with their PBS prescription, they will pay the PBS co-payment and that the amount will count towards their Safety Net
3. Familiarise themselves with the process for PBS prescribing of ODT medicines under the Section 100 HSD Program (apply for a PBS prescriber number if necessary)
4. Ensure sufficient stock of PBS stationery, if necessary.
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1. Note: The PBS Closing the Gap Co-payment Measure does not include Section 100 medicines. [↑](#footnote-ref-1)
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](http://www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence) [↑](#footnote-ref-2)