**An addendum to this Public Summary Document has been included at the end of the document.**

**OOS Post-market Review of medicines for the treatment of opioid dependence**

1. Purpose of Item

That the Pharmaceutical Benefits Advisory Committee (PBAC):

* 1. Consider the interim report for the Post-market Review (PMR) of medicines for the treatment of opioid dependence (‘the Review’) addressing Review terms of reference (TORs) 1-4 (and Executive Summary).
  2. Note the stakeholder input to the PMR, including the consultation with people participating in opioid dependence treatment (ODT) programs (refer Appendix 3 of the interim report).
  3. Comment on the interim outcomes arising from Review and provide early advice on a proposed recommendation to change the current Pharmaceutical Benefits Scheme (PBS) listings for ODT medicines to the Section 100 Highly Specialised Drugs (HSD) Program (Community Access).
  4. Note the draft restrictions for buprenorphine (sublingual tablets and modified release injections), buprenorphine with naloxone (sublingual films) and methadone (oral liquid) to be PBS listed under the Section 100 HSD Program (Community Access).

1. Background
   1. Medicines available for the treatment of opioid dependence (noted above at 1.4) are currently listed under the Section 100 Opioid Dependence Treatment Program (ODTP).
   2. Currently patients are subject to significant out-of-pocket pharmacy dosing fees ($140-$224 a month compared to general and concessional PBS co-payments of $30 and $7.30 respectively) in the absence of the usual PBS listings for these medicines, which mean that patient co-payments are not nationally regulated, and the PBS Safety Net arrangements do not apply to reduce costs for patients who reach the threshold.
   3. While most patients (80%) access ODT medicines from community pharmacy dosing points, there is also a large proportion of medicines for ODT dispensed throughout Australia within correctional facilities.
   4. The operation of ODT programs is managed by state and territory governments in line with their program policies and guidelines. Prescribers and pharmacies must comply with the provisions of State/Territory regulations for controlled drugs when prescribing and dispensing these medicines.
   5. On 22 November 2022, the Chair of the PBAC responded to a letter from the Minister for Health and Aged Care, the Hon Mark Butler MP, recommending the PBAC present an early report to government on the Review to ensure the government can effectively respond to the legislative amendment which requires Section 100 programs on the PBS, such as the ODTP, to be made via a legislative instrument from 1 July 2023.
   6. A preliminary utilisation report using data from the National Opioid Pharmacotherapy Statistic Annual Data collection and Commonwealth ODTP expenditure data was considered by the Drug Utilisation Sub-Committee (DUSC) in June 2022.
2. Current Situation
   1. To assist the government in meeting the 1 July 2023 timeframe, the department provided the PBAC with an interim Review report to seek early advice on the Review outcomes. The key findings for individual TORs are in the Executive Summary as well as in the TOR chapters of the interim Review report.
   2. Over December 2022/January 2023 the Department sought feedback from the Review Reference Group on the draft PMR report. Members of the Review Reference Group raised strong concerns that the draft report did not adequately solve for the core issue of affordability for all ODT medicines and noted significant access limitations with only listing long-acting injectable buprenorphine under Section 85.
   3. The advice of Reference Group Members on the draft report has been considered by the Department and the report revised, noting that in view of the 1 July 2023 deadline, timeframes to resolve the listing of ODT medicines are constrained.
3. Approach to address patient affordability and access
   1. To address the core issues of patient affordability and equitable access to ODT medicines, the report suggested the PBAC consider the option of a revised Section 100 listing of ODT medicines in a way that aligns more with existing PBS arrangements including the PBS   
      co-payment and Safety Net.
   2. The PBAC was asked to respond to this Review outcome by providing its in-principle support to change the way ODT medicines are listed on the PBS, by listing all PBS ODT medicines under an existing program – the Section 100 HSD Program (Community Access).
   3. The option of maintaining the status quo or delaying changes to the way ODT medicines are listed on the PBS is not the preferred approach as it will mean patients will continue to be charged unregulated private fees that do not count towards the Safety Net threshold or, if delayed, that the 1 July 2023 timeframe may not be met.
   4. Listing under the Section 100 HSD Program (Community Access) will mean patients will have access to PBS co-payments and Safety-Net provisions, prisoner access to ODT medicines will be maintained (as prisoner access to PBS medicines is already facilitated under the Section 100 HSD Program) and that pharmacies will receive PBS dispensing fees.
   5. It also means that registration of a legislative instrument for the ODTP will not be required (as ODT medicines will be listed under the Section 100 HSD Program legislative instrument). The use of an existing Section 100 program structure from 1 July 2023 will benefit patients sooner through a more straightforward implementation with Services Australia and will also assist the government in responding to the 1 July 2023 timeframe to resolve these matters.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

1. Proposed revised listing for ODT medicines

To achieve a Section 100 HSD program listing ODT medicines are proposed to be listed as follows:

* 1. All ODT medicines would be dispensed on a 28-day basis similar to other PBS medicines listed on the Section 100 HSD Program. As with other PBS medicines, medicines would attract one PBS co-payment per month per strength dispensed and patient contributions would count towards the PBS Safety-Net threshold.
  2. Pharmacists would receive PBS dispensing fees set out under the Section 100 HSD Program. In addition is also anticipated that community pharmacists will receive payments under a separate community pharmacy program for activities associated with in-pharmacy and take-away dosing (so patients are no longer charged private dosing fees). This program would be similar to the existing Staged Supply Program under the Seventh Community Pharmacy Agreement.
  3. Methadone would be remunerated on a per mL basis up to a maximum of 840 mL which is equivalent to a maximum dose of 150 mg (30 mL) daily x 28 days in line with national guidelines[[1]](#footnote-1). This means pharmacists will be able to continue to share a 1 L bottle of methadone between multiple patients if necessary.
  4. Buprenorphine tables and buprenorphine and naloxone film would be remunerated on a per pack basis up to a maximum dose of 32 mg (4 x 8 mg tablet or 8 mg / 2 mg film)1. A prescription will be required for each of the strengths required to make up the required dose. For example, 26 mg daily of buprenorphine = 3 x 8 mg tablets and 1 x 2 mg tablets daily resulting in maximum quantities of 12 packs and 4 packs containing 7 tablets, respectively, over 28 days.
  5. Long-acting buprenorphine weekly injections would be remunerated up to a maximum quantity of 4 injections, and the monthly injections a maximum quantity of 1 injection, per 28 days.
  6. Prescribers would be encouraged to prescribe only the quantities and repeats that are suitable for the patient’s clinical needs until the next review, for example lower or no repeats during initiation.

*For more detail on PBAC’s view, see section 6 PBAC outcome.*

1. PBAC Outcome
   1. The PBAC considered the interim report for the ODTP PMR addressing the Review TOR and noted the stakeholder input to the PMR, including targeted consultation with people participating in ODT programs.
   2. The PBAC accepted the key findings presented in the interim Review Report.
   3. The PBAC acknowledged the issues of affordability and equity under current Section 100 ODTP arrangements and supported a solution to address these in a nationally consistent manner in line with the principles outlined in the interim report.
   4. The PBAC noted that listing under the Section 100 HSD Program (Community Access) will mean patients will have access to PBS co-payments and Safety-Net provisions, prisoner access to ODT medicines will be maintained (as prisoner access to PBS medicines is already facilitated under the Section 100 HSD Program) and that pharmacies will receive PBS dispensing fees.
   5. The PBAC considered that introducing remuneration arrangements for community pharmacists that align with other S100 PBS medicines would encourage increased participation from community pharmacies thereby improving accessibility for patients. However, the PBAC also noted the additional activities associated with the dispensing of ODT medicines that have more frequent dispensing requirements (such as oral methadone and sublingual buprenorphine) and the need to ensure pharmacists are remunerated appropriately so this is not a cost borne by patients.
   6. The PBAC acknowledged that prescribers and pharmacies would continue to be required to comply with jurisdictional policy and the provisions of State/Territory regulations for controlled drugs and noted there would likely be some ODT patients for whom support through public treatment options would continue to be required.
   7. The PBAC provided in-principle support for moving ODT medicines to a Section 100 HSD Program (Community Access) listing commencing 1 July 2023 and noted the draft restrictions.
   8. The PBAC endorsed the development of an option for consideration by government for community pharmacies, in line with state and territory regulations and guidelines to administer buprenorphine injections under particular circumstances.
   9. The PBAC requested the government progress discussions with state and territory governments on matters relating to the current variable nature and models of service delivery used to provide ODT, jurisdictional dosing policies, and the maintenance of access to treatment through jurisdictional public treatment options.
   10. The PBAC endorsed an update to the *2014 National Guidelines for Medication-Assisted Treatment of Opioid Dependence* be progressed*.*
   11. The PBAC requested the government progress discussions regarding workforce issues with state and territory governments.
   12. The PBAC acknowledged the specific matters raised in the review with respect to access to ODT medicines for First Nations and other populations with specific needs and requested government progress discussions on these matters with state and territory governments.

**Outcome:**

Advice Provided

Addendum to the OOS March 2023 PBAC Public Summary Document:

**OOS Post-market Review of medicines for the treatment of opioid dependence**

1. Purpose
   1. At an out of session meeting between its March 2023 and July 2023 meeting, the PBAC provided in-principle support for moving ODT medicines currently listed on the PBS under the Section 100 Opiate Dependence Treatment Program (ODTP) to a Section 100 HSD Program (Community Access) listing and noted the draft restrictions.
   2. ODT medicines listed on the ODTP include buprenorphine (sublingual tablets and modified release injections), buprenorphine with naloxone (sublingual films) and methadone (oral liquid).
   3. A formal recommendation was sought to assist the government in meeting the 1 July 2023 timeframe.
2. PBAC Outcome
   1. The PBAC recommended the current listing of ODT medicines on the PBS Section 100 Opiate Dependence Treatment Program be amended and the listing moved to the Section 100 Highly Specialised Drugs (HSD) Program (Community Access) as Authority Required (STREAMLINED) listings.
   2. The PBAC noted the PBS financial impact associated with implementing this listing under the Section 100 HSD Program commencing 1 July 2023 is expected to be low and that cost estimates would be finalised by the Department out of session.
   3. The PBAC recommended patients should have access to up to 28 day’s supply per dispensing with a maximum of two repeats and asked for the revised listings for ODT medicines to have maximum quantities and repeats that reflect this for standard dosing*.*
   4. The PBAC recommended that the Early Supply Rule should apply.
   5. The PBAC advised that methadone, buprenorphine, and buprenorphine with naloxone continue to be suitable for prescribing by nurse practitioners.
   6. The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

1. Recommended listing
   1. Amend existing listings:

Additions are in italic and deletions are in strikethrough.

**Methadone**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **Form** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of Rpts** | **Available brands** |
| METHADONE | | | | | | | |
| methadone hydrochloride 5 mg/mL oral liquid, 1 L | | | ~~6172W~~  New | ~~1~~ *0.84* | ~~1~~ *840 ml\** | *2* | aAspen Methadone Syrup  aBiodone Forte |
| methadone hydrochloride 5 mg/mL oral liquid, 200 mL | | | ~~6171T~~  New | ~~1~~ *4.2* | ~~1~~ *840 ml* | *2* | aAspen Methadone Syrup  aBiodone Forte |
|  | | | | | | | |
| **Restriction Summary [new1] / Treatment of Concept: [new2]** | | | | | | | |
| **Concept ID** (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:** Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code: new2) | | | | | |
|  |  | **~~Caution:~~**  ~~The risk of drug dependence is high.~~ | | | | | |
|  | **Administrative Advice:**  Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice:**  Shared Care Model:  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | |  | | | | | |
|  | | ***Clinical criteria:*** | | | | | |
|  | | *The treatment must be within a framework of medical, social and psychological treatment* | | | | | |
|  | |  | | | | | |
|  | | ***Prescribing instructions:***  *A medical practitioner 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 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.* | | | | | |

\*NB: This maximum quantity will allow for daily doses up to 150 mg = 30 mL daily (840 mL over 28 days).

**Buprenorphine tablets**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **Form** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **No of repeats** | **Available Brands** |
| BUPRENORPHINE | | | | | | | |
| buprenorphine 400 microgram sublingual tablet, 7 | | | ~~6307Y~~  New | ~~1~~ *4* | ~~7~~ *28* | *2* | Subutex® |
| buprenorphine 2 mg sublingual tablet, 7 | | | ~~6308B~~  New | ~~1~~ *12* | ~~7~~ *84* | *2* | Subutex® |
| buprenorphine 8 mg sublingual tablet, 7 | | | ~~6309C~~  New | ~~1~~ *16* | ~~7~~ *112\*\** | *2* | Subutex® |
|  | | | | | | | |
| **Restriction Summary [New1] / Treatment of Concept: [New2]:** | | | | | | | |
| **Concept ID** (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:** Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code: New2) | | | | | |
|  |  | ***Administrative Advice:***  *Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment*. | | | | | |
|  | **Administrative Advice:** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice: Shared Care Model:**  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners**.** | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | |  | | | | | |
|  | | **~~Treatment Phase:~~** ~~Maintenance and detoxification (withdrawal)~~ | | | | | |
|  | |  | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | The treatment must be within a framework of medical, social and psychological treatment | | | | | |
|  | |  | | | | | |
|  | | ***Prescribing instructions:***  *A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient’s daily dose. Up to 2 repeats will be authorised. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.* | | | | | |

\*\*NB – This maximum quantity is based on a maximum dose of 32 mg daily.

**Buprenorphine plus naloxone film**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **Form** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **No of repeats** | **Available brands** |
| BUPRENORPHINE WITH NALOXONE | | | | | | | |
| buprenorphine 2 mg + naloxone 500  microgram sublingual film, 28 | | | ~~9749D~~  New | ~~1~~ *3* | ~~28~~ *84* | *2* | Suboxone film 2/0.5 |
| buprenorphine 8 mg + naloxone 2 mg sublingual film, 28 | | | ~~9750E~~  New | ~~1~~ *4* | ~~28~~ 112\*\* | *2* | Suboxone film 8/2 |
|  | | | | | | | |
| **Restriction Summary [New1] / Treatment of Concept: [New2]:** | | | | | | | |
| **Concept ID** (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:** Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code: New2) | | | | | |
|  |  | **Administrative Advice:**  Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment. | | | | | |
|  | **Administrative Advice:** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice: Shared Care Model:**  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners**.** | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | |  | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | The treatment must be within a framework of medical, social and psychological treatment | | | | | |
|  | |  | | | | | |
|  | | ***Prescribing instructions:***  *A medical practitioner must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient’s daily dose. Up to 2 repeats will be authorised.. A medical practitioner must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.* | | | | | |

\*\*NB – This maximum quantity is based on a maximum dose of 32 mg daily (of buprenorphine).

**Long-acting injectable buprenorphine**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **medicinal product pack** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of**  **Rpts** | **Available brands** |
| BUPRENORPHINE | | | | | | | |
| Buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe | | | ~~11759X~~  New | *~~1~~ 4* | *~~1~~ 4* | *~~0~~ 2* | Buvidal weekly® |
| Buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe | | | ~~11774Q~~  New | *~~1~~ 4* | *~~1~~ 4* | *~~0~~ 2* |
| Buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe | | | ~~11773P~~  New | *~~1~~ 4* | *~~1~~ 4* | *~~0~~ 2* |
| Buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe | | | ~~11766G~~  New | *~~1~~ 4* | *~~1~~ 4* | *~~0~~ 2* |
|  | | | | | | | |
| **Restriction Summary ~~9213~~ New1/ Treatment of Concept: ~~9212~~ New2** | | | | | | | |
| **Concept ID**  (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:** Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code: New2) | | | | | |
|  |  | **Administrative Advice:**  Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice:**  **Shared Care Model:**  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
|  | ***Administrative advice:***  *No increase in the maximum quantity or number of units may be authorised.* | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | | **Treatment criteria:** | | | | | |
|  | | Must be treated by a health care professional | | | | | |
|  | | **AND** | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | The treatment must be within a framework of medical, social and psychological treatment | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **medicinal product pack** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of**  **Rpts** | **Available brands** |
| BUPRENORPHINE | | |  | | | | |
| Buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe | | | ~~11754P~~  NEW | 1 | 1 | *~~0~~2* | Buvidal Monthly® |
| Buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe | | | ~~11767H~~  NEW | 1 | 1 | *~~0~~2* |
| Buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe | | | ~~11768J~~  NEW | 1 | 1 | *~~0~~2* |
| Buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe | | | ~~12981F~~  NEW | 1 | 1 | *~~0~~2* |
|  | | | | | | | |
| **Restriction Summary ~~9213~~ New1/ Treatment of Concept: ~~9212~~ New2** | | | | | | | |
| **Concept ID**  (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:** Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code New2) | | | | | |
|  |  | **Administrative Advice:**  Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice:**  **Shared Care Model:**  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
|  | ***Administrative advice:***  *No increase in the maximum quantity or number of units may be authorised.* | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | | **Treatment criteria:** | | | | | |
|  | | Must be treated by a health care professional | | | | | |
|  | | **AND** | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | The treatment must be within a framework of medical, social and psychological treatment | | | | | |
|  | | **AND** | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | 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 | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **MEDICINAL PRODUCT**  **medicinal product pack** | | | **PBS item code** | **Max. qty packs** | **Max. qty units** | **№.of**  **Rpts** | **Available brands** |
| BUPRENORPHINE | | |  | | | | |
| Buprenorphine 100 mg/0.5 mL modified release injection, syringe | | | ~~11987X~~  New | 1 | 1 | ~~0~~ 2 | Sublocade® |
| Buprenorphine 300 mg/1.5 mL modified release injection, syringe | | | ~~11990C~~  New | 1 | 1 | ~~0~~ 2 |
|  | | | | | | | |
| **Restriction Summary ~~9213~~ New1/ Treatment of Concept: ~~9212~~ New2** | | | | | | | |
| **Concept ID**  (for internal Dept. use) | | **Category / Program:** Section 100 – ~~Opiate Dependence~~ HSD (Community Access) | | | | | |
| **Prescriber type:**  Medical Practitioners Nurse practitioners | | | | | |
| **Restriction type:**  Authority Required (STREAMLINED) (code New2) | | | | | |
|  |  | **Administrative Advice:**  Care must be taken to comply with the provisions of State/Territory law when prescribing this drug. | | | | | |
|  | **Administrative Advice:**  **Shared Care Model:**  For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners. | | | | | |
|  | ***Administrative advice:***  *No increase in the maximum quantity or number of units may be authorised.* | | | | | |
|  | ***Administrative Advice:***  *No increase in the maximum number of repeats may be authorised.* | | | | | |
|  | |  | | | | | |
|  | | **Indication:** ~~Opiate~~ *Opioid* dependence | | | | | |
|  | | **Treatment criteria:** | | | | | |
|  | | Must be treated by a health care professional | | | | | |
|  | | **AND** | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | The treatment must be within a framework of medical, social and psychological treatment | | | | | |
|  | | **AND** | | | | | |
|  | | **Clinical criteria:** | | | | | |
|  | | Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition | | | | | |

***This restriction may be subject to further review. Should there be any changes made to the restriction the sponsors will be informed*.**

1. Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

1. Sponsor’s Comment

**Indivior**

Indivior welcomes the Australian Government’s commitment to improve access and address inequity in the ODTP and supports the PBAC’s advice on how those aims can be achieved. This measure recognises the importance of enhancing the availability of ODT to improve the health of vulnerable Australians.

**Camurus**

Camurus thanks the contributors to the Interim ODTP PMR Report for their thorough examination of the ODTP and the emphasis given to the experience of patients unable to access the program due to affordability. Camurus will continue to work with the Department to address any outstanding concerns.

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](http://www.health.gov.au/resources/publications/national-guidelines-for-medication-assisted-treatment-of-opioid-dependence) [↑](#footnote-ref-1)