11.03 TGA Prescription Opioid Regulatory Reforms

1. Purpose
   1. To request that the Pharmaceutical Benefits Advisory Committee (PBAC) consider proposed changes to the restrictions for opioids on the Pharmaceutical Benefits Scheme (PBS).
2. Background
   1. In July 2019, in response to a submission sponsored by Mundipharma Pty Ltd, the PBAC recommended the Restricted Benefit listing of a new maximum quantity (MQ) of 10 for oxycodone 5 mg capsules and tablets. In making its recommendation, the PBAC noted the requirements of section 85D of the *National Health Act 1953* (the Act), that different pack sizes of the same pharmaceutical item are to be priced proportionally and requested the Department negotiate a price for the 10 pack consistent with these requirements.
   2. The PBAC recommended the new listing for a MQ of 10 for oxycodone be differentiated from the current listing for a MQ of 20 by indicating that the smaller quantity is intended for short-term (2-3 days) relief of acute severe pain that is unresponsive to non-opioid analgesics, and by not allowing any increase in the MQ or number of repeats.
   3. The PBAC acknowledged the potential quality use of medicine benefit of reduced MQs for opioids used in the acute pain setting (e.g. after surgery) (oxycodone, OxyNorm PSD, July 2019 PBAC meeting[[1]](#footnote-1)).
3. Current situation
   1. The Therapeutic Goods Administration (TGA) was undertaking regulatory measures which aimed to reduce the harms associated with prescription opioid dependence and inappropriate use, including overdose fatalities. The regulatory measures were based on the findings from the TGA’s 2018 prescription opioid review, and advice received from the Opioid Regulatory Advisory Group (ORAG). The regulatory measures and associated timing are summarised in Table 1. Some of these measures had implications for the PBS.
   2. The TGA had advised that while these regulatory measures would play a significant role in reducing subsequent harms associated with inappropriate prescription use, other organisations and stakeholders heavily influence the wider environment and patient community to which these products are provided. The TGA had worked with ORAG, and across government and other stakeholders to identify activities to support the appropriate use of opioids, including:

extensive education and awareness campaigns by the TGA, professional medical indemnity insurers, and peak prescriber and pharmacist associations,

changes to clinical guidelines,

ensuring that sponsors comply with the requirements of the Therapeutic Goods Act 1989, by only promoting the new narrower indications when advertising to prescribers.

integration of the changes into policies and regulatory schemes administered by jurisdictional health departments,

utilisation of real time prescription monitoring programs, and continuing to monitor prescriber compliance to the Department’s health payment requirements.

Table 1: TGA opioid reform regulatory measures and associated timing and issues

| Regulatory measures | TGA timing and remit under the *Therapeutic Goods Act 1989* |
| --- | --- |
| 1. Registration of **smaller pack sizes** for immediate release opioid products indicated for acute pain, including oxycodone, tramadol, tramadol/paracetamol, paracetamol/codeine, codeine, hydromorphone, morphine, tapentadol, and buprenorphine. | **12-24 months from January 2020**  The TGA has existing powers to compel registration but not the supply of smaller packs. |
| 1. Restricting the **indications** for fentanyl patches to the management of pain associated with cancer, palliative care and other conditions in opioid-tolerant patients where:    * other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient pain management, and    * the pain is opioid-responsive, and    * the pain is severe enough to require daily, continuous, long-term opioid treatment.    * Not for use in opioid naïve patients. | **6 months from Oct 2019**  The TGA has existing powers to amend the indication for safety reasons.  The innovator sponsor, Janssen-Cilag, is expected to complete its Product Information (PI) update by the end of 2019, with the three generic sponsors to follow soon after (generic sponsors are required to reflect safety information in the innovator PI). |
| 1. Revised indications for immediate- and modified-release prescription opioids as follows.     **Modified release (MR) products** (buprenorphine transdermal patches, dihydrocodeine SR tablets, hydromorphone SR tablet/capsules, morphine SR tablets and granules, oxycodone SR tablets, tapentadol SR tablets, tramadol SR tablets, injection and oral drops, methadone tablets and injections):  [Product] is indicated for the management of severe pain where:  o other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain, and  o the pain is opioid-responsive, and  o requires daily, continuous, long term treatment.  [Product] is not indicated for use in chronic non-cancer pain other than in exceptional circumstances.  [Product] is not indicated as an as-needed (PRN) analgesia.  Not for use in opioid naïve patients. (Hydromorphone and fentanyl patches only)  **Immediate release (IR) products** (buprenorphine injections and sublingual tablets, codeine tablets and injections, hydromorphone injections, oral liquid and tablets, morphine oral solution and injections and tablets, oxycodone liquid and solution for infusion/injection, pethidine injection, tapentadol tablets, tramadol/paracetamol tablets):  [Product] is indicated for the short-term management of severe pain for which other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain. | **12-24 months from Oct 2019**  The TGA has existing powers to amend the PI on the grounds of safety. |
| 1. **Boxed warnings** and class statements in the PI of all prescription opioids, and stronger warnings in the **Consumer Medicines Information** (CMI)**.** | **12-24 months from Oct 2019**  The TGA has existing powers to amend the PI on the grounds of safety. There are existing regulations to ensure the CMI reflects the PI. However, the updating of the CMI content is the sponsor’s responsibility. |

Source: <https://www.tga.gov.au/opioid-reforms-information-sponsors>

1. Smaller pack sizes for immediate-release opioids
   1. Table 2 lists the products in scope which are currently listed on the PBS for pain management and would be appropriate for listing for acute pain. Items that are currently restricted for chronic pain, pain due to cancer or palliative care have not been included.
   2. The Secretariat had proposed new Restricted Benefit listings with a smaller MQ (as per Table 2), with no repeats or increased quantities. The proposed clinical criteria indicated that the smaller quantity is intended for short-term therapy of acute severe disabling pain which is unresponsive to non-opioid analgesics in patients who have previously experienced inadequate pain relief following maximum tolerated doses of non-opioid treatments or who are unable to use other non-opioid treatments due to contraindications or intolerance.
   3. Section 85D of the Act requires that different pack sizes of the same pharmaceutical item are to be priced proportionally. The Secretariat noted that the ex-manufacturer price for the smaller MQ would need to be agreed between the Government and the relevant sponsors in line with this requirement, as per the PBAC’s July 2019 recommendation for oxycodone 5 mg (see paragraph 2.2).
   4. Sponsors would be required to register the new smaller pack sizes with the TGA within 24 months from January 2020. However, the TGA does not have existing powers to require sponsors to supply the smaller pack sizes. Prior to the smaller pack sizes being available, the Secretariat proposed that the new listings be created at the smaller MQ for the drugs that have a tablet or capsule form, as outlined in Table 2. This would require pharmacists to break the larger available packs.
   5. The Government remunerates pharmacists if they need to dispense a quantity less than the manufacturer’s pack size listed on the PBS. The remuneration comprises of a wastage fee based on the proportion of the pack supplied, in addition to the applicable dispensing fee, dangerous drug fee (if applicable), and appropriate container fee. In some cases, the DPMQ for the broken pack is larger than the DPMQ for the current MQ. The DPMQ for the new listings with the smaller MQ (including the broken pack fees) for each of the opioid products is provided in Table 2.

Table 2: PBS listed products in scope for the smaller pack sizes regulatory measure

| LI Drug | LI Forms | PBS item codes | MQA | DPMQ  (as at 1 Dec 2019) | Tablets per blister in currently available pack size | TGA proposed new pack sizeB | Proposed smaller MQB | DPMQ for smaller MQ (including broken pack fees) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Codeine** | Tablet containing codeine phosphate hemihydrate 30 mg | 1214X 5063L | 20 | $20.06 | 2 x 10 tablet blisters | 10 | 10 | $19.47 |
| **Codeine with paracetamol** | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | 1215Y  3316M | 20 | $12.83 | 2 x 10 tablet blisters | 10 to 12 | 10 | $13.81 |
| **Hydromorphone** | Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL | 11467M 11479E | 1 | $45.88 | n/a | 20mL | 1 C | n/a C |
| Tablet containing hydromorphone hydrochloride 2 mg | 5115F 8541M | 20 | $21.18 | 20 tablets within the bottle | 10 | 10 | $20.17 |
| Tablet containing hydromorphone hydrochloride 4 mg | 5116G 8542N | 20 | $23.45 | 20 tablets within the bottle | 10 | 10 | $21.57 |
| Tablet containing hydromorphone hydrochloride 8 mg | 5117H 8543P | 20 | $31.86 | 20 tablets within the bottle | 10 | 10 | $26.79 |
| **Morphine** | Tablet containing morphine sulfate pentahydrate 30 mg | 1646P 5163R | 20 | $18.85 | 2 x 10 tablet blisters | 6 to 10 | 10 | $18.72 |
| **Oxycodone** | Capsule containing oxycodone hydrochloride 5 mg | 5191F 8464L | 20 | $16.91 | 2 x 10 capsule blisters | 6 to 10 | 10 | $17.52 |
| Tablet containing oxycodone hydrochloride 5 mg | 2622B  5195K | 20 | $16.54 | 2 x 10 tablet blisters | 6 to 10 | 10 | $17.29 |
| Capsule containing oxycodone hydrochloride 10 mg | 5197M 8501K | 20 | $19.19 | 2 x 10 capsule blisters | 6 to 10 | 10 | $18.93 |
| Oral liquid containing oxycodone hydrochloride 1 mg per mL, 250 mL | 5190E 8644Y | 1 (250mL) | $27.83 | n/a | 20mL to 30mLD | 1 C | n/a C |
| **Tramadol** | Capsule containing tramadol hydrochloride 50 mg | 5232J 8455B | 20 | $13.48 | 2 blisters x 10 | 6 to 10 | 10 | $14.21 |

A MQ aligns with the currently available pack size

B Where the TGA had proposed a range for the new smaller pack size, the Secretariat had proposed the MQ be in line with the tablets per blister sheet in the currently available pack (i.e. a smaller MQ of 10 has been proposed for a pack of 20 with 2 x 10 tablet blister sheets) on the assumption that this would be the most likely pack size that sponsors would register.

C For liquid formulations it will not be possible to create new listings with a smaller MQ until a smaller pack size is available.

D The Secretariat proposed that the PBAC recommend oxycodone in the form of oral liquid containing oxycodone hydrochloride 1 mg per mL in a bottle with volume ranging from 20-30mL at the same price per mg as the current 250 mL listing.

* 1. While prescribers already have the ability to prescribe smaller amounts of these drugs using the current PBS items, creating new listings with smaller MQs would provide a simple way for prescribers to prescribe smaller quantities of immediate release opioids for acute pain, prior to the smaller pack sizes being available. If the new listings resulted in fewer patients being prescribed a greater quantity of opioids than required for acute pain, then patients would have fewer tablets remaining following their treatment and there would consequently be fewer prescription opioids circulating in the community.
  2. Estimates of the net cost to the PBS/RPBS of creating new listings at the smaller MQ, including broken pack fees, are summarised in Table 3. Current PBS data indicated that over 60% of scripts for the immediate-release opioids listed in Table 2 are for only one pack of drug and may therefore have been intended to treat short-term acute pain. The financial estimates in Table 3 were based on an assumption that 60% of scripts for these products would be for the new smaller MQ listings going forward. This is likely to be an overestimate as some of the current prescriptions for one pack of the current MQ would likely to be clinically required for a proportion of these patients. The estimated cost of the new listings with the smaller MQ (including broken pack fees) based on this conservative assumption is around $3.0 million per year.

**Table 3: Estimated net cost to PBS/RPBS as a result of new smaller MQ listings for immediate** **release opioids**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | 2020 | 2021 | 2022 | 2023 | 2024 |
| Net cost to PBS/RPBS | $2,962,731 | $2,965,033 | $2,965,706 | $2,964,031 | $2,985,690 |

* 1. As the smaller pack sizes become available, the net cost to the PBS/RPBS will immediately reduce. However, this was not factored in to the estimates as the timing of the introduction of smaller packs is uncertain. Further, the estimates do not take into account whether the prescribing of immediate-release opioids overall may reduce as a result of the revisions to the TGA indications and proposed changes to the PBS restrictions (see sections 5 and 6, Revised indications for fentanyl and immediate- and modified release opioids).
  2. Sensitivity analyses were conducted to estimate an upper and lower limit of the net costs. If 99% of scripts switched to the smaller MQ, the net cost to the PBS/RPBS was estimated to be around $4.9 million per year. If only 20% of scripts switched to the smaller MQ, the net cost was estimated to be around $1.0 million per year.
  3. Almost all of the estimated costs were due to two listings: paracetamol 500 mg + codeine phosphate hemihydrate 30 mg tablet (item 1215Y) and oxycodone hydrochloride 5 mg tablet (item 2622B). This was due to the relatively low approved ex-manufacturer price of these products compared with the compensation paid to pharmacists for breaking packs and to the high forecast volume of scripts (around 2.5 million prescriptions per year for each drug).

1. Narrower indications for fentanyl patches
   1. The TGA wrote to the sponsors of fentanyl patch products in October 2019, requiring that they update their Product Information (PI) documents with the revised indication as outlined in Table 1.
   2. Fentanyl patches are currently listed as Restricted Benefits on the General Schedule of the PBS for patients with chronic severe disabling pain whose condition is unresponsive to non-opioid analgesics.
   3. The TGA has advised that the intent of the ‘other conditions in opioid-tolerant patients…’ section of the restriction was to cater to patients for whom other prescription opioids have been determined to be inappropriate; for example, patients with end stage renal failure, as well as those who may have issues with swallowing oral medicines. Furthermore, this category addresses long-term users of fentanyl patches, for whom it would be difficult to safely switch to another pain relief option. The TGA further clarified that the intent of the revised restriction was to ensure that the number of new patients using fentanyl patches is reduced, rather than to require patients who are currently reliant on the patches to move to other pain relief. However, there is an expectation that prescribers will identify patients who are currently prescribed fentanyl patches outside of the cancer pain and palliative care setting to consider weaning patients where it is appropriate and safe to do so.
   4. The Secretariat proposed revisions to the PBS restrictions for fentanyl patches, to align these restrictions with the amended TGA indications, including changing the listings to be Authority Required (STREAMLINED).
   5. While the TGA had stated the changes to PIs would occur within 6 months from October 2019, the Secretariat noted that given the changes are narrower than the current TGA registered indications, the changes could be made to PBS listings before they are made to the PIs.
2. Revised indications for immediate- and modified-release opioids
   1. The TGA advised that it would ask relevant sponsors to update their PIs to reflect that the use of modified release opioids in chronic non-cancer pain is no longer indicated except in exceptional circumstances. In addition, changes were also being made to indications for immediate-release opioids to harmonise the indications across all products. Not all of the proposed indication changes put forward by the TGA had implications for PBS listing: some of the identified brands were not listed on the PBS and others already had restrictions that aligned with the revised TGA indications.
   2. The Secretariat noted that the TGA opioid review had defined opioids as for either short-term or long-term use. For the purposes of reviewing PBS listings, the Secretariat proposed sub-categorising into first-line and second-line treatments, in accordance with the current Therapeutic Guidelines. First-line opioids would be for use in patients who have not responded to, are intolerant to or whose condition would not respond to non-opioid analgesics; second-line opioids would be used if other opioids (either first- or second-line) and non-opioid analgesics had failed or been deemed to provide inadequate pain relief.
   3. The Secretariat proposed revisions to the immediate and modified-release opioids listed on the PBS for pain management to align with the proposed new TGA indications. The main types of changes proposed were:

* items that are currently Unrestricted will become Restricted Benefits for severe pain that is unresponsive to non-opioid analgesia; and
* items that are currently indicated for chronic severe disabling pain unresponsive to non-opioid analgesics will be updated to reflect that they should only be used for cancer pain or in palliative care except in exceptional circumstances.
  1. While the TGA had stated that the changes to PIs would occur within 12-24 months from October 2019, the Secretariat noted that given the changes are narrower than the current TGA registered indications, the changes could be made to PBS listings before they are made to PIs.

1. Boxed warnings and class statements
   1. The TGA advised that warnings and statements would be prominently displayed on the PIs and CMIs of all prescription opioid products registered in Australia.
   2. The Secretariat proposed that the caution ‘the risk of drug dependence is high’ be applied consistently across all of the relevant listings.
2. PBAC Outcome
   1. The PBAC recommended changes to opioids listed on the PBS as below (and detailed in section 9):

* implementing new Restricted Benefit listings for smaller MQs of immediate release opioids with no increased quantities or repeats (as identified in Table 2) for patients requiring short-term relief of acute severe pain that is unresponsive to non-opioid analgesics;
* amending the listings for immediate- and modified-release opioids (outlined in para 8.7 and section 9 in detail) to support the appropriate prescribing and use of opioids.
  1. The PBAC noted that the TGA would be requiring sponsors to register new smaller pack sizes for some immediate-release opioid analgesics, and considered that additional PBS listings with smaller MQs could reduce the number of patients prescribed a greater quantity of opioids than required for acute severe pain.
  2. The PBAC considered that the smaller MQs for immediate-release opioids would provide sufficient quantity for acute pain relief at the lowest effective dose, but also considered that in some acute pain settings, a larger quantity may be required. The PBAC therefore chose not to limit the duration of treatment for acute pain to a set number of days, and considered that the proposed criteria was sufficient to direct prescribers as to the appropriate prescribing of these opioids.
  3. The PBAC noted that the smaller MQ listings would be priced proportionally to the existing listings, in accordance with the requirements of Section 85D of the Act.
  4. The PBAC noted that the smaller MQs would require pharmacists to dispense less than the whole amount of a standard pack size (i.e. to break a pack), and that the Government compensates pharmacists for this. The PBAC noted that, due to the broken pack fees, the estimated net cost to the PBS was approximately $3 million per year.
  5. The PBAC considered that it was clinically appropriate for these listings to be created prior to sponsors releasing registered new pack sizes of these products, and noted that the costs would reduce once a smaller pack size of at least one brand of an affected item is listed on the PBS. The PBAC advised the Department that once it is able to secure the supply and listing of a smaller pack size for an item with a smaller MQ, it would be appropriate to pursue the removal of the reduced MQ conditions on the larger pack size listings with the intent of ceasing the supply of broken packs and encouraging the use of the smaller pack size in an acute setting.
  6. The PBAC noted that the TGA had revised the indications of several opioid analgesics, including fentanyl patches, to broadly categorise them into opioids for acute severe pain and for chronic severe pain. The PBAC recommended that the PBS restrictions for immediate- and modified-release opioids should be changed in the following manner to align with the TGA indication changes:
* Opioids for short-term use in the first-line setting (codeine tablets, codeine + paracetamol tablets, tramadol capsule, injection, and oral drops, and oxycodone tablets, capsules, suppository, and oral solution) to be Restricted Benefits limited to patients who have not responded to, are intolerant to or whose condition would not respond to non-opioid analgesics;
* Opioids for short-term use in the second-line setting (hydromorphone tablets, injections, and oral liquid, morphine tablets, oral solution and injections) to be Restricted Benefits limited to patients who have not responded to, are intolerant to or whose condition would not respond to non-opioid nor other opioid analgesics.
* Opioids for long-term use in the first-line setting (buprenorphine transdermal patches, morphine capsules, tablets and granules, oxycodone tablets, oxycodone with naloxone tablets, tapentadol tablets, and tramadol tablets) to have authority level increased to Authority Required (STREAMLINED) for daily, continuous, long-term management of pain due to cancer or who have not responded to, are intolerant to or who experience inadequate pain management at maximum doses of non-opioid or other opioid analgesics.
* Opioids for long-term use in the second-line setting (hydromorphone tablets, methadone tablets and injection, fentanyl transdermal patches) to have authority level increased to Authority Required (STREAMLINED) with the same restrictions as opioids in the long-term first-line setting with the additional requirement that the patient must not be opioid-naïve, and the additional advice to “Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication”.
  1. The PBAC considered that the exceptional circumstances referred to in the revised TGA indications were adequately encompassed in the revised opioid restrictions in Section 9. The PBAC also considered that the proposed revisions to the PBS restrictions for fentanyl patches aligned with the amended TGA indications for fentanyl patches.
  2. The PBAC noted that the opioids for long-term use in the first- and second-line settings identified in paragraph 8.7 are currently listed as Restricted Benefits on the PBS. The PBAC recommended an increase in the authority level to Authority Required (STREAMLINED) in line with the aims of the TGA’s opioid reforms. The PBAC also noted that, as is currently the case for these items, authority requests for increased quantities to extend treatment up to one month will still need to be made by telephone, and treatment beyond one month and up to three months will require a written authority requesting additional repeats. The PBAC also noted that a streamlined authority code would enhance the ability for the Department of Health to undertake utilisation analyses and compliance activities to identify inappropriate prescribing.
  3. The PBAC noted that paracetamol with codeine had two listings, one of which allowed up to a 6 month supply on a single script with a written authority. The PBAC noted that this was inconsistent with the other opioids listings on the PBS, for which written authority for increased quantity and repeats can only provide a supply for up to 3 months. The PBAC considered that this listing should be brought in line with all other opioid analgesics, noting that it may result in an increased volume of authority requests to the Department of Human Services. The PBAC also considered that the proposed restriction changes outlined in paragraph 8.7 would achieve this consistency and also encompass the intent of the new TGA indication for short-term pain management. The PBAC therefore considered that there should only be one listing for paracetamol with codeine as proposed, and that the additional listing should be deleted.
  4. The PBAC noted that tramadol immediate release tablets also had two restricted benefits listings, one indicated for acute pain with no repeats, and another indicated for dose-titration in chronic pain with 2 repeats. The PBAC considered that there was no need for a specific dose-titration listing, and that the proposed restriction changes outlined in paragraph 8.7 would encompass the intent of the existing listings as well as the intent of the new TGA indication for short-term pain management. The PBAC therefore considered that there should only be one listing for tramadol immediate release tablets as proposed, and that the listing for dose-titration should be deleted.
  5. The PBAC noted that a recent revision of the Therapeutic Guidelines recommended that dentists should not prescribe codeine for pain relief. Although the PBAC was of a mind to recommend the removal of dental practitioner prescribing from the PBS listings for codeine, it asked the Department to first consult with the Australian Dental Association before making a final recommendation on the matter.
  6. The PBAC expressed its concern regarding the high number of deaths and hospitalisations caused by prescription opioids in Australia, and acknowledged the significant work being undertaken by the TGA to help tackle the problem. The PBAC considered that its recommended changes to opioid listings on the PBS would complement the TGA’s efforts to support the safe and clinically appropriate use of opioids while recognising the important role they play in providing pain relief for many people.
  7. The PBAC noted that the regulatory changes and recommended changes to PBS listings will be implemented as part of a broader suite of measures intended to support appropriate use of opioids, including education and awareness campaigns, changes to clinical guidelines and ongoing prescription and compliance monitoring.

1. Recommended Listings

**Contents**

[***TGA short-term pain indication: proposed PBS restrictions in 1st line setting*** 15](#_Toc32300578)

[**Listing 1: Restriction for short-term pain TGA indication in 1st line opioid setting (excluding oxycodone suppositories):** 15](#_Toc32300579)

[**Listing 2: Restriction for short-term pain TGA indication in 1st line opioid setting (oxycodone suppositories):** 18](#_Toc32300580)

[**Listing 3: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting (excluding oxycodone suppositories):** 20](#_Toc32300581)

[**Listing 4: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting (oxycodone suppositories):** 22](#_Toc32300582)

[**Listing 5: Restriction for codeine in the body system: RESPIRATORY SYSTEM > COUGH AND COLD PREPARATIONS > COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS:** 23](#_Toc32300583)

[***TGA short-term pain indication: proposed PBS restrictions in 2nd line setting*** 24](#_Toc32300584)

[**Listing 6: Restriction for short-term pain TGA indication in 2nd line opioid setting (excluding Sevredol, and morphine injections):** 24](#_Toc32300585)

[**Listing 7: Restriction for short-term cancer pain TGA indication in 2nd line opioid setting (Sevredol):** 27](#_Toc32300586)

[**Listing 8: Restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections):** 29](#_Toc32300587)

[**Listing 9: Restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections available to midwives):** 31](#_Toc32300588)

[**Listing 10: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting (excluding morphine injections):** 33](#_Toc32300589)

[**Listing 11: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections):** 34](#_Toc32300590)

[***Proposed PBS restrictions for reduced pack sizes in 1st line setting*** 36](#_Toc32300591)

[**Listing 12: Restriction for short-term pain TGA indication in 1st line opioid setting:** 36](#_Toc32300592)

[**Listing 13: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting:** 38](#_Toc32300593)

[***Proposed PBS restrictions for reduced pack sizes in 2nd line setting*** 40](#_Toc32300594)

[**Listing 14: Restriction for short-term pain TGA indication in 2nd line opioid setting:** 40](#_Toc32300595)

[**Listing 15: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting:** 41](#_Toc32300596)

[***TGA long-term pain indication: proposed PBS restrictions in 1st line setting*** 42](#_Toc32300597)

[**Listing 16: Restriction for long-term pain TGA indication in 1st line opioid setting (excluding morphine 200 mg forms and oxycodone):** 42](#_Toc32300598)

[**Listing 17a: Restriction for long-term pain TGA indication in 1st line opioid setting (morphine 200 mg MR tablets and 200mg granules):** 48](#_Toc32300599)

[**Listing 17b: Restriction for long-term pain TGA indication in 1st line opioid setting (morphine 200 mg MR tablets and 200mg granules):** 49](#_Toc32300600)

[**Listing 18: Restriction for long-term pain TGA indication in 1st line opioid setting (oxycodone MR tablet – without naloxone – 15 mg and 30 mg):** 51](#_Toc32300601)

[**Listing 19: Restriction for long-term pain TGA indication in 1st line opioid setting (oxycodone MR tablet – without naloxone – 10 mg, 20 mg, 40 mg and 80 mg):** 53](#_Toc32300602)

[***TGA long-term pain indication: proposed PBS restrictions in 2nd line setting*** 55](#_Toc32300603)

[**Listing 20: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 12mcg/hr patch):** 55](#_Toc32300604)

[**Listing 21: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 25mcg/hr patch):** 57](#_Toc32300605)

[**Listing 22: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 50mcg/hr patch):** 59](#_Toc32300606)

[**Listing 23: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 75mcg/hr patch):** 61](#_Toc32300607)

[**Listing 24: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 100mcg/hr patch):** 63](#_Toc32300608)

[**Listing 25: Restriction for long-term pain TGA indication in 2nd line opioid setting (hydromorphone MR tablets):** 65](#_Toc32300609)

[**Listing 26: Restriction for long-term pain TGA indication in 2nd line opioid setting (methadone injection and IR tablet):** 67](#_Toc32300610)

***TGA short-term pain indication: PBS restrictions in 1st line setting***

* 1. Amend items:

**Listing 1: Restriction for short-term pain TGA indication in 1st line opioid setting (excluding oxycodone suppositories):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| CODEINE | 1214X | Tablet containing codeine phosphate hemihydrate 30 mg | 20 | 0 | Aspen Pharma Pty Ltd | Aspen Pharma Pty Ltd |
| CODEINE WITH PARACETAMOL | 1215Y | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | 20 | 0 | APO- Paracetamol/Codeine 500/30 | Apotex Pty Ltd |
|  |  |  |  | Codalgin Forte | Alphapharm Pty Ltd |
|  |  |  |  | Codapane Forte 500/30 | Alphapharm Pty Ltd |
|  |  |  |  | Comfarol Forte | Sandoz Pty Ltd |
|  |  |  |  | Panadeine Forte | sanofi-aventis Australia Pty Ltd |
|  |  |  |  | Paracetamol/Codeine GH 500/30 | Generic Health Pty Ltd |
|  |  |  |  |  | Prodeine Forte | sanofi-aventis Australia Pty Ltd |
| OXYCODONE | 8501K | Capsule containing oxycodone hydrochloride 10 mg | 20 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 8502L | Capsule containing oxycodone hydrochloride 20 mg | 20 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 8464L | Capsule containing oxycodone hydrochloride 5 mg | 20 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 8644Y | Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL | 1 | 0 | OxyNorm Liquid 1mg/mL | Mundipharma Pty Limited |
|  | 2622B | Tablet containing oxycodone hydrochloride 5 mg | 20 | 0 | Endone | Alphapharm Pty Ltd |
|  |  |  |  | Mayne Pharma Oxycodone IR | Mayne Pharma International Pty Ltd |
|  |  |  |  | Oxycodone Aspen | Alphapharm Pty Ltd |
| TRAMADOL | 8455B | Capsule containing tramadol hydrochloride 50 mg | 20 | 0 | APO-Tramadol | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol | Apotex Pty Ltd |
|  |  |  |  | Tramadol AMNEAL | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SCP | Pharmacor Pty Limited |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo | Alphapharm Pty Ltd |
|  |  |  |  | Zydol | Arrow Pharma Pty Ltd |
| TRAMADOL | 8582Q | Injection containing tramadol hydrochloride 100 mg in 2 mL | 5 | 0 | Tramadol ACT | Juno Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Juno Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal 100 | Seqirus (Australia) Pty Ltd |
| TRAMADOL | 8843K | Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL | 1 | 0 | Tramal | Seqirus (Australia) Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with proven malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) severe disabling pain associated with proven malignant neoplasia; or  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020 |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Delete item: 8611F
  2. Delete item: 8785J
  3. Amend item:

**Listing 2: Restriction for short-term pain TGA indication in 1st line opioid setting (oxycodone suppositories):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| OXYCODONE | 2481N | Suppository 30 mg (as pectinate) | 12 | 0 | Proladone | Phebra Pty Ltd |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [18096] Patient must have cancer pain  OR  [new] The treatment must be for post-operative pain following a major operative procedure  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with proven malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months |
| **Clinical criteria:** | [18096] Patient must have cancer pain  OR  [new] The treatment must be for post-operative pain following a major operative procedure  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) severe disabling pain associated with proven malignant neoplasia; or  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020 |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020 |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 3: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting (excluding oxycodone suppositories):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| CODEINE | 5063L | Tablet containing codeine phosphate hemihydrate 30 mg | 20 | 0 | Aspen Pharma Pty Ltd | Aspen Pharma Pty Ltd |
| CODEINE WITH PARACETAMOL | 3316M | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | 20 | 0 | APO- Paracetamol/Codeine 500/30 | Apotex Pty Ltd |
|  |  |  |  | Codalgin Forte | Alphapharm Pty Ltd |
|  |  |  |  | Codapane Forte 500/30 | Alphapharm Pty Ltd |
|  |  |  |  | Comfarol Forte | Sandoz Pty Ltd |
|  |  |  |  | Panadeine Forte | sanofi-aventis Australia Pty Ltd |
|  |  |  |  | Paracetamol/Codeine GH 500/30 | Generic Health Pty Ltd |
|  |  |  |  | Prodeine Forte | sanofi-aventis Australia Pty Ltd |
| OXYCODONE | 5197M | Capsule containing oxycodone hydrochloride 10 mg | 20 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 5191F | Capsule containing oxycodone hydrochloride 5 mg | 20 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 5190E | Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL | 1 | 0 | OxyNorm Liquid 1mg/mL | Mundipharma Pty Limited |
|  | 5195K | Tablet containing oxycodone hydrochloride 5 mg | 20 | 0 | Endone | Alphapharm Pty Ltd |
|  |  |  |  | Mayne Pharma Oxycodone IR | Mayne Pharma International Pty Ltd |
|  |  |  |  | Oxycodone Aspen | Alphapharm Pty Ltd |
| TRAMADOL | 5232J | Capsule containing tramadol hydrochloride 50 mg | 20 | 0 | APO-Tramadol | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol | Apotex Pty Ltd |
|  |  |  |  | Tramadol AMNEAL | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SCP | Pharmacor Pty Limited |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo | Alphapharm Pty Ltd |
|  |  |  |  | Zydol | Arrow Pharma Pty Ltd |
|  | 5231H | Injection containing tramadol hydrochloride 100 mg in 2 mL | 5 | 0 | Tramadol ACT | Juno Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Juno Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal 100 | Seqirus (Australia) Pty Ltd |
|  | 5150C | Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL | 1 | 0 | Tramal | Seqirus (Australia) Pty Ltd |

|  |  |
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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend item:

**Listing 4: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting (oxycodone suppositories):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| OXYCODONE | 5194J | Suppository 30 mg (as pectinate) | 12 | 0 | Proladone | Phebra Pty Ltd |

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|  | **Category / Program:** | GENERAL – General Schedule (Code GE) |
|  | **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
|  | **PBS indication:** | [7861] Severe pain |
|  | **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
|  | **Clinical criteria:** | [new] Treatment must be for post-operative pain following a major operative procedure  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
|  | **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. |
|  | **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Add new items:

**Listing 5: Restriction for codeine in the body system: RESPIRATORY SYSTEM > COUGH AND COLD PREPARATIONS > COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| CODEINE | 1214X | Tablet containing codeine phosphate hemihydrate 30 mg | 20 | 0 | Aspen Pharma Pty Ltd | Aspen Pharma Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Cough |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] Treatment must be for cough suppression. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

***TGA short-term pain indication: PBS restrictions in 2nd line setting***

* 1. Amend items:

**Listing 6: Restriction for short-term pain TGA indication in 2nd line opioid setting (excluding Sevredol, and morphine injections):**

| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| --- | --- | --- | --- | --- | --- | --- |
| HYDROMORPHONE | 8421F | Injection containing hydromorphone hydrochloride 10 mg in 1 mL | 5 | 0 | Dilaudid-HP | Mundipharma Pty Limited |
|  |  |  |  | HYDROMORPHONE JUNO-HP | Juno Pharmaceuticals Pty Ltd |
|  | 8420E | Injection containing hydromorphone hydrochloride 2 mg in 1 mL | 5 | 0 | Dilaudid | Mundipharma Pty Limited |
|  |  |  |  | HYDROMORPHONE JUNO | Juno Pharmaceuticals Pty Ltd |
|  | 11467M | Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL | 1 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8541M | Tablet containing hydromorphone hydrochloride 2 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8542N | Tablet containing hydromorphone hydrochloride 4 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8543P | Tablet containing hydromorphone hydrochloride 8 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
| MORPHINE | 2124T | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL | 1 | 0 | Ordine 10 | Mundipharma Pty Limited |
|  | 2122Q | Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL | 1 | 0 | Ordine 2 | Mundipharma Pty Limited |
|  | 2123R | Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL | 1 | 0 | Ordine 5 | Mundipharma Pty Limited |
|  | 1646P | Tablet containing morphine sulfate pentahydrate 30 mg | 20 | 0 | Anamorph | Arrow Pharma Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with proven malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) severe disabling pain associated with proven malignant neoplasia; or  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020 |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend item:

**Listing 7: Restriction for short-term cancer pain TGA indication in 2nd line opioid setting (Sevredol):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 8669G | Tablet containing morphine sulfate pentahydrate 10 mg | 20 | 0 | Sevredol | Mundipharma Pty Limited |
|  | 8670H | Tablet containing morphine sulfate pentahydrate 20 mg | 20 | 0 | Sevredol | Mundipharma Pty Limited |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [New] Cancer pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [18096] Patient must have cancer pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [New] Cancer pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [18096] Patient must have cancer pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [New] Cancer pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 8: Restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 10878M | Injection containing morphine hydrochloride trihydrate 100 mg in 5 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 10874H | Injection containing morphine hydrochloride trihydrate 20 mg in 1 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 10869C | Injection containing morphine hydrochloride trihydrate 50 mg in 5 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 1647Q | Injection containing morphine sulfate pentahydrate 30 mg in 1 mL | 5 | 0 | Hospira Pty Limited  MORPHINE SULFATE 30 mg/1 mL MEDSURGE | Pfizer Australia Pty Ltd  Medsurge Healthcare Pty Ltd |
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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance  OR  [new] The treatment must be part of pre-operative care  OR  [new] The treatment must be used as an analgesic adjunct in general anaesthesia. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with proven malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance  OR  [new] The treatment must be part of pre-operative care  OR  [new] The treatment must be used as an analgesic adjunct in general anaesthesia. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) severe disabling pain associated with proven malignant neoplasia; or  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020 |
| **Clinical criteria:** | Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 9: Restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections available to midwives):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | LI Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 10864T | Injection containing morphine hydrochloride trihydrate 10 mg in 1 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 1644M | Injection containing morphine sulfate pentahydrate 10 mg in 1 mL | 5 | 0 | Hospira Pty Limited | Pfizer Australia Pty Ltd |
|  |  |  |  | MORPHINE SULFATE 10 mg/1 mL MEDSURGE | Medsurge Healthcare Pty Ltd |
|  | 1645N | Injection containing morphine sulfate pentahydrate 15 mg in 1 mL | 5 | 0 | Hospira Pty Limited | Pfizer Australia Pty Ltd |
|  |  |  |  | MORPHINE SULFATE 15 mg/1 mL MEDSURGE | Medsurge Healthcare Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance  OR  [new] The treatment must be part of pre-operative care  OR  [new] The treatment must be used as an analgesic adjunct in general anaesthesia. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for severe disabling pain associated with proven malignant neoplasia or chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [18949] Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance  OR  [new] The treatment must be part of pre-operative care  OR  [new] The treatment must be used as an analgesic adjunct in general anaesthesia. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for:  (i) severe disabling pain associated with proven malignant neoplasia; or  (ii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [18949] Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020 |
| **Clinical criteria:** | Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instructions:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority approval for:  (i) severe disabling pain associated with malignant neoplasia; or  (ii) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months; or  (iii) palliative care patients with chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient is unable to have annual pain management review due to their clinical condition; or  (iv) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [18949] Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution.  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 10: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting (excluding morphine injections):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| HYDROMORPHONE | 11479E | Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL | 1 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5115F | Tablet containing hydromorphone hydrochloride 2 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5116G | Tablet containing hydromorphone hydrochloride 4 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5117H | Tablet containing hydromorphone hydrochloride 8 mg | 20 | 0 | Dilaudid | Mundipharma Pty Limited |
| MORPHINE | 5239R | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL | 1 | 0 | Ordine 10 | Mundipharma Pty Limited |
|  | 5237P | Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL | 1 | 0 | Ordine 2 | Mundipharma Pty Limited |
|  | 5238Q | Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL | 1 | 0 | Ordine 5 | Mundipharma Pty Limited |
|  | 5163R | Tablet containing morphine sulfate pentahydrate 30 mg | 20 | 0 | Anamorph | Arrow Pharma Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 11: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting (morphine injections):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 10863R | Injection containing morphine hydrochloride trihydrate 10 mg in 1 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 10858L | Injection containing morphine hydrochloride trihydrate 20 mg in 1 mL | 5 | 0 | Morphine Juno | Juno Pharmaceuticals Pty Ltd |
|  | 5168B | Injection containing morphine sulfate pentahydrate 10 mg in 1 mL | 5 | 0 | Hospira Pty Limited | Pfizer Australia Pty Ltd |
|  |  |  |  |  | Medsurge Healthcare Pty Ltd |
|  | 5169C | Injection containing morphine sulfate pentahydrate 15 mg in 1 mL | 5 | 0 | Hospira Pty Limited | Pfizer Australia Pty Ltd |
|  |  |  |  | MORPHINE SULFATE 15 mg/1 mL MEDSURGE | Medsurge Healthcare Pty Ltd |
|  | 5170D | Injection containing morphine sulfate pentahydrate 30 mg in 1 mL | 5 | 0 | Hospira Pty Limited | Pfizer Australia Pty Ltd |
|  |  |  |  | MORPHINE SULFATE 30 mg/1 mL MEDSURGE | Medsurge Healthcare Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance.  OR  [new] The treatment must be part of pre-operative care  OR  [new] The treatment must be used as an analgesic adjunct in general anaesthesia. |
| **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.  [18949] Pharmaceutical benefits that have the forms morphine sulfate 10 mg/mL injection and morphine hydrochloride 10 mg/mL injection are equivalent for the purposes of substitution. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

***PBS restrictions for reduced pack sizes in 1st line setting***

* 1. Add new items:

**Listing 12: Restriction for short-term pain TGA indication in 1st line opioid setting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| CODEINE | 1214X | Tablet containing codeine phosphate hemihydrate 30 mg | 10 | 0 | Aspen Pharma Pty Ltd | Aspen Pharma Pty Ltd |
| CODEINE WITH PARACETAMOL | 1215Y | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | 10 | 0 | APO- Paracetamol/Codeine 500/30 | Apotex Pty Ltd |
|  |  |  |  | Codalgin Forte | Alphapharm Pty Ltd |
|  |  |  |  | Codapane Forte 500/30 | Alphapharm Pty Ltd |
|  |  |  |  | Comfarol Forte | Sandoz Pty Ltd |
|  |  |  |  | Panadeine Forte | sanofi-aventis Australia Pty Ltd |
|  |  |  |  | Paracetamol/Codeine GH 500/30 | Generic Health Pty Ltd |
|  |  |  |  | Prodeine Forte | sanofi-aventis Australia Pty Ltd |
| OXYCODONE | 8501K | Capsule containing oxycodone hydrochloride 10 mg | 10 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 8464L | Capsule containing oxycodone hydrochloride 5 mg | 10 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 8644Y | Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL | 1 | 0 | OxyNorm Liquid 1mg/mL | Mundipharma Pty Limited |
|  | 2622B | Tablet containing oxycodone hydrochloride 5 mg | 10 | 0 | Endone | Alphapharm Pty Ltd |
|  |  |  |  | Mayne Pharma Oxycodone IR | Mayne Pharma International Pty Ltd |
|  |  |  |  | Oxycodone Aspen | Alphapharm Pty Ltd |
| TRAMADOL | 8455B | Capsule containing tramadol hydrochloride 50 mg | 10 | 0 | APO-Tramadol | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol | Apotex Pty Ltd |
|  |  |  |  | Tramadol AMNEAL | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SCP | Pharmacor Pty Limited |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo | Alphapharm Pty Ltd |
|  |  |  |  | Zydol | Arrow Pharma Pty Ltd |
|  | 8843K | Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL | 1 | 0 | Tramal | Seqirus (Australia) Pty Ltd |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] The treatment must be for short term therapy of acute severe pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [7606] No increase in the maximum quantity or number of units may be authorised.  [7607] No increase in the maximum number of repeats may be authorised. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Add new items:

**Listing 13: Dentists’ restriction for short-term pain TGA indication in 1st line opioid setting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| CODEINE | 5063L | Tablet containing codeine phosphate hemihydrate 30 mg | 10 | 0 | Aspen Pharma Pty Ltd | Aspen Pharma Pty Ltd |
|  | 3316M | Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg | 10 | 0 | APO- Paracetamol/Codeine 500/30 | Apotex Pty Ltd |
|  |  |  |  | Codalgin Forte | Alphapharm Pty Ltd |
|  |  |  |  | Codapane Forte 500/30 | Alphapharm Pty Ltd |
|  |  |  |  | Comfarol Forte | Sandoz Pty Ltd |
|  |  |  |  | Panadeine Forte | sanofi-aventis Australia Pty Ltd |
|  |  |  |  | Paracetamol/Codeine GH 500/30 | Generic Health Pty Ltd |
|  |  |  |  | Prodeine Forte | sanofi-aventis Australia Pty Ltd |
| OXYCODONE | 5197M | Capsule containing oxycodone hydrochloride 10 mg | 10 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 5191F | Capsule containing oxycodone hydrochloride 5 mg | 10 | 0 | OxyNorm | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone BNM | Luminarie Pty Ltd |
|  | 5190E | Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL | 1 | 0 | OxyNorm Liquid 1mg/mL | Mundipharma Pty Limited |
|  | 5195K | Tablet containing oxycodone hydrochloride 5 mg | 10 | 0 | Endone | Alphapharm Pty Ltd |
|  |  |  |  | Mayne Pharma Oxycodone IR | Mayne Pharma International Pty Ltd |
|  |  |  |  | Oxycodone Aspen | Alphapharm Pty Ltd |
| TRAMADOL | 5232J | Capsule containing tramadol hydrochloride 50 mg | 10 | 0 | APO-Tramadol | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol | Apotex Pty Ltd |
|  |  |  |  | Tramadol AMNEAL | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SCP | Pharmacor Pty Limited |
|  |  |  |  | Tramadol Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Tramal | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo | Alphapharm Pty Ltd |
|  |  |  |  | Zydol | Arrow Pharma Pty Ltd |
|  | 5150C | Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL | 1 | 0 | Tramal | Seqirus (Australia) Pty Ltd |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] The treatment must be for short term therapy of acute severe pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid analgesics  OR  [new] Patient must be unable to use non-opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

***PBS restrictions for reduced pack sizes in 2nd line setting***

* 1. Add new items:

**Listing 14: Restriction for short-term pain TGA indication in 2nd line opioid setting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| HYDROMORPHONE | 11467M | Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL | 1 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8541M | Tablet containing hydromorphone hydrochloride 2 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8542N | Tablet containing hydromorphone hydrochloride 4 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 8543P | Tablet containing hydromorphone hydrochloride 8 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
| MORPHINE | 2124T | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL | 1 | 0 | Ordine 10 | Mundipharma Pty Limited |
|  | 2122Q | Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL | 1 | 0 | Ordine 2 | Mundipharma Pty Limited |
|  | 2123R | Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL | 1 | 0 | Ordine 5 | Mundipharma Pty Limited |
|  | 1646P | Tablet containing morphine sulfate pentahydrate 30 mg | 10 | 0 | Anamorph | Arrow Pharma Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] The treatment must be for short term therapy of acute severe pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [7606] No increase in the maximum quantity or number of units may be authorised.  [7607] No increase in the maximum number of repeats may be authorised. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Add new items:

**Listing 15: Dentists’ restriction for short-term pain TGA indication in 2nd line opioid setting:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| HYDROMORPHONE | 11479E | Oral liquid containing hydromorphone hydrochloride 1 mg per mL, 200 mL | 1 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5115F | Tablet containing hydromorphone hydrochloride 2 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5116G | Tablet containing hydromorphone hydrochloride 4 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
|  | 5117H | Tablet containing hydromorphone hydrochloride 8 mg | 10 | 0 | Dilaudid | Mundipharma Pty Limited |
| MORPHINE | 5239R | Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL | 1 | 0 | Ordine 10 | Mundipharma Pty Limited |
|  | 5237P | Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL | 1 | 0 | Ordine 2 | Mundipharma Pty Limited |
|  | 5238Q | Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL | 1 | 0 | Ordine 5 | Mundipharma Pty Limited |
|  | 5163R | Tablet containing morphine sulfate pentahydrate 30 mg | 10 | 0 | Anamorph | Arrow Pharma Pty Ltd |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [7861] Severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] The treatment must be for short term therapy of acute severe pain  AND  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

***TGA long-term pain indication: PBS restrictions in 1st line setting***

* 1. Amend items:

**Listing 16: Restriction for long-term pain TGA indication in 1st line opioid setting (excluding morphine 200 mg forms and oxycodone):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| BUPRENORPHINE | 8866P | Transdermal patch 10 mg | 2 | 0 | Bupredermal | Apotex Pty Ltd |
|  |  |  |  | Buprenorphine Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Norspan | Mundipharma Pty Limited |
|  | 10770W | Transdermal patch 15 mg | 2 | 0 | Buprenorphine Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Norspan | Mundipharma Pty Limited |
|  | 8867Q | Transdermal patch 20 mg | 2 | 0 | Bupredermal | Apotex Pty Ltd |
|  |  |  |  | Buprenorphine Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Norspan | Mundipharma Pty Limited |
|  | 10756D | Transdermal patch 25 mg | 2 | 0 | Norspan | Mundipharma Pty Limited |
|  | 10755C | Transdermal patch 30 mg | 2 | 0 | Norspan | Mundipharma Pty Limited |
|  | 10746N | Transdermal patch 40 mg | 2 | 0 | Norspan | Mundipharma Pty Limited |
|  | 8865N | Transdermal patch 5 mg | 2 | 0 | Bupredermal | Apotex Pty Ltd |
|  |  |  |  | Buprenorphine Sandoz | Sandoz Pty Ltd |
|  |  |  |  | Norspan | Mundipharma Pty Limited |
| MORPHINE | 8349K | Capsule containing morphine sulfate pentahydrate 10 mg (containing sustained release pellets) | 28 | 0 | Kapanol | Mayne Pharma International Pty Ltd |
|  | 2841M | Capsule containing morphine sulfate pentahydrate 100 mg (containing sustained release pellets) | 28 | 0 | Kapanol | Mayne Pharma International Pty Ltd |
|  | 8494C | Capsule containing morphine sulfate pentahydrate 120 mg (controlled release) | 14 | 0 | MS Mono | Mundipharma Pty Limited |
|  | 2839K | Capsule containing morphine sulfate pentahydrate 20 mg (containing sustained release pellets) | 28 | 0 | Kapanol | Mayne Pharma International Pty Ltd |
|  | 8491X | Capsule containing morphine sulfate pentahydrate 30 mg (controlled release) | 14 | 0 | MS Mono | Mundipharma Pty Limited |
|  | 2840L | Capsule containing morphine sulfate pentahydrate 50 mg (containing sustained release pellets) | 28 | 0 | Kapanol | Mayne Pharma International Pty Ltd |
|  | 8492Y | Capsule containing morphine sulfate pentahydrate 60 mg (controlled release) | 14 | 0 | MS Mono | Mundipharma Pty Limited |
|  | 8493B | Capsule containing morphine sulfate pentahydrate 90 mg (controlled release) | 14 | 0 | MS Mono | Mundipharma Pty Limited |
|  | 8306E | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 100 mg per sachet | 28 | 0 | MS Contin Suspension 100 mg | Mundipharma Pty Limited |
|  | 8490W | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 20 mg per sachet | 28 | 0 | MS Contin Suspension 20 mg | Mundipharma Pty Limited |
|  | 8146R | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 30 mg per sachet | 28 | 0 | MS Contin Suspension 30 mg | Mundipharma Pty Limited |
|  | 8305D | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 60 mg per sachet | 28 | 0 | MS Contin Suspension 60 mg | Mundipharma Pty Limited |
|  | 1653B | Tablet containing morphine sulfate pentahydrate 10 mg (controlled release) | 28 | 0 | MORPHINE MR APOTEX | Apotex Pty Ltd |
|  |  |  |  | MS Contin | Mundipharma Pty Limited |
|  |  |  |  | Momex SR 10 | Arrow Pharma Pty Ltd |
|  |  |  |  | Morphine MR AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Morphine MR Mylan | Alphapharm Pty Ltd |
|  | 1656E | Tablet containing morphine sulfate pentahydrate 100 mg (controlled release) | 28 | 0 | MORPHINE MR APOTEX | Apotex Pty Ltd |
|  |  |  |  | MS Contin | Mundipharma Pty Limited |
|  |  |  |  | Momex SR 100 | Arrow Pharma Pty Ltd |
|  |  |  |  | Morphine MR AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Morphine MR Mylan | Alphapharm Pty Ltd |
|  | 8489T | Tablet containing morphine sulfate pentahydrate 15 mg (controlled release) | 28 | 0 | MS Contin | Mundipharma Pty Limited |
|  | 1654C | Tablet containing morphine sulfate pentahydrate 30 mg (controlled release) | 28 | 0 | MORPHINE MR APOTEX | Apotex Pty Ltd |
|  |  |  |  | MS Contin | Mundipharma Pty Limited |
|  |  |  |  | Momex SR 30 | Arrow Pharma Pty Ltd |
|  |  |  |  | Morphine MR AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Morphine MR Mylan | Alphapharm Pty Ltd |
|  | 8035X | Tablet containing morphine sulfate pentahydrate 5 mg (controlled release) | 28 | 0 | MS Contin | Mundipharma Pty Limited |
|  | 1655D | Tablet containing morphine sulfate pentahydrate 60 mg (controlled release) | 28 | 0 | MORPHINE MR APOTEX | Apotex Pty Ltd |
|  |  |  |  | MS Contin | Mundipharma Pty Limited |
|  |  |  |  | Momex SR 60 | Arrow Pharma Pty Ltd |
|  |  |  |  | Morphine MR AN | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Morphine MR Mylan | Alphapharm Pty Ltd |
| OXYCODONE WITH NALOXONE | 8934F | Tablet (controlled release) containing oxycodone hydrochloride 10 mg with naloxone hydrochloride 5 mg | 28 | 0 | Targin 10/5mg | Mundipharma Pty Limited |
|  | 10757E | Tablet (controlled release) containing oxycodone hydrochloride 15 mg with naloxone hydrochloride 7.5 mg | 28 | 0 | Targin 15/7.5mg | Mundipharma Pty Limited |
|  | 10776E | Tablet (controlled release) containing oxycodone hydrochloride 2.5 mg with naloxone hydrochloride 1.25 mg | 28 | 0 | Targin 2.5/1.25 mg | Mundipharma Pty Limited |
|  | 8935G | Tablet (controlled release) containing oxycodone hydrochloride 20 mg with naloxone hydrochloride 10 mg | 28 | 0 | Targin 20/10mg | Mundipharma Pty Limited |
|  | 10758F | Tablet (controlled release) containing oxycodone hydrochloride 30 mg with naloxone hydrochloride 15 mg | 28 | 0 | Targin 30/15 mg | Mundipharma Pty Limited |
|  | 8936H | Tablet (controlled release) containing oxycodone hydrochloride 40 mg with naloxone hydrochloride 20 mg | 28 | 0 | Targin 40/20mg | Mundipharma Pty Limited |
|  | 8000C | Tablet (controlled release) containing oxycodone hydrochloride 5 mg with naloxone hydrochloride 2.5 mg | 28 | 0 | Targin 5/2.5mg | Mundipharma Pty Limited |
|  | 11102H | Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg | 28 | 0 | Targin 60/30 | Mundipharma Pty Limited |
|  | 11111T | Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg | 28 | 0 | Targin 80/40 | Mundipharma Pty Limited |
| TAPENTADOL | 10094G | Tablet (modified release) 100 mg (as hydrochloride) | 28 | 0 | Palexia SR | Seqirus (Australia) Pty Ltd |
|  | 10100N | Tablet (modified release) 150 mg (as hydrochloride) | 28 | 0 | Palexia SR | Seqirus (Australia) Pty Ltd |
|  | 10091D | Tablet (modified release) 200 mg (as hydrochloride) | 28 | 0 | Palexia SR | Seqirus (Australia) Pty Ltd |
|  | 10092E | Tablet (modified release) 250 mg (as hydrochloride) | 28 | 0 | Palexia SR | Seqirus (Australia) Pty Ltd |
|  | 10096J | Tablet (modified release) 50 mg (as hydrochloride) | 28 | 0 | Palexia SR | Seqirus (Australia) Pty Ltd |
| TRAMADOL | 8523N | Tablet (sustained release) containing tramadol hydrochloride 100 mg | 20 | 0 | APO-Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Tramadol AN SR | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SR generichealth | Generic Health Pty Ltd |
|  |  |  |  | Tramadol Sandoz SR | Sandoz Pty Ltd |
|  |  |  |  | Tramal SR 100 | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo SR | Alphapharm Pty Ltd |
|  |  |  |  | Zydol SR 100 | Arrow Pharma Pty Ltd |
|  | 8524P | Tablet (sustained release) containing tramadol hydrochloride 150 mg | 20 | 0 | APO-Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Tramadol AN SR | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SR generichealth | Generic Health Pty Ltd |
|  |  |  |  | Tramadol Sandoz SR | Sandoz Pty Ltd |
|  |  |  |  | Tramal SR 150 | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo SR | Alphapharm Pty Ltd |
|  |  |  |  | Zydol SR 150 | Arrow Pharma Pty Ltd |
|  | 8525Q | Tablet (sustained release) containing tramadol hydrochloride 200 mg | 20 | 0 | APO-Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Chem mart Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Terry White Chemists Tramadol SR | Apotex Pty Ltd |
|  |  |  |  | Tramadol AN SR | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Tramadol SR generichealth | Generic Health Pty Ltd |
|  |  |  |  | Tramadol Sandoz SR | Sandoz Pty Ltd |
|  |  |  |  | Tramal SR 200 | Seqirus (Australia) Pty Ltd |
|  |  |  |  | Tramedo SR | Alphapharm Pty Ltd |
|  |  |  |  | Zydol SR 200 | Arrow Pharma Pty Ltd |
|  | 2527B | Tablet (sustained release) containing tramadol hydrochloride 50 mg | 20 | 0 | Tramal SR 50 | Seqirus (Australia) Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 17a: Restriction for long-term pain TGA indication in 1st line opioid setting (morphine 200 mg MR tablets and 200mg granules):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 8454Y | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet | 28 | 0 | MS Contin Suspension 200 mg | Mundipharma Pty Limited |
|  | 8453X | Tablet containing morphine sulfate pentahydrate 200 mg (controlled release) | 28 | 0 | MS Contin | Mundipharma Pty Limited |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Administrative advice:** | [7606] No increase in the maximum quantity or number of units may be authorised.  [7607] No increase in the maximum number of repeats may be authorised.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333. |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Add new items:

**Listing 17b: Restriction for long-term pain TGA indication in 1st line opioid setting (morphine 200 mg MR tablets and 200mg granules):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Existing Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| MORPHINE | 8454Y | Sachet containing controlled release granules for oral suspension, containing morphine sulfate pentahydrate 200 mg per sachet | 28 | 0 | MS Contin Suspension 200 mg | Mundipharma Pty Limited |
|  | 8453X | Tablet containing morphine sulfate pentahydrate 200 mg (controlled release) | 28 | 0 | MS Contin | Mundipharma Pty Limited |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 18: Restriction for long-term pain TGA indication in 1st line opioid setting (oxycodone MR tablet – without naloxone – 15 mg and 30 mg):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| OXYCODONE | 9399Q | Tablet containing oxycodone hydrochloride 15 mg (controlled release) | 28 | 0 | OxyContin | Mundipharma Pty Limited |
|  | 9400R | Tablet containing oxycodone hydrochloride 30 mg (controlled release) | 28 | 0 | OxyContin | Mundipharma Pty Limited |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [10909] OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [10909] OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [10909] OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 19: Restriction for long-term pain TGA indication in 1st line opioid setting (oxycodone MR tablet – without naloxone – 10 mg, 20 mg, 40 mg and 80 mg):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| OXYCODONE | 8385H | Tablet containing oxycodone hydrochloride 10 mg (controlled release) | 28 | 0 | Novacodone | Sandoz Pty Ltd |
|  |  |  |  | OxyContin | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone Sandoz | Sandoz Pty Ltd |
|  | 8386J | Tablet containing oxycodone hydrochloride 20 mg (controlled release) | 28 | 0 | Novacodone | Sandoz Pty Ltd |
|  |  |  |  | OxyContin | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone Sandoz | Sandoz Pty Ltd |
|  | 8387K | Tablet containing oxycodone hydrochloride 40 mg (controlled release) | 28 | 0 | Novacodone | Sandoz Pty Ltd |
|  |  |  |  | OxyContin | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone Sandoz | Sandoz Pty Ltd |
|  | 8388L | Tablet containing oxycodone hydrochloride 80 mg (controlled release) | 28 | 0 | Novacodone | Sandoz Pty Ltd |
|  |  |  |  | OxyContin | Mundipharma Pty Limited |
|  |  |  |  | Oxycodone Sandoz | Sandoz Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [21221] OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term opioid treatment  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid or other opioid analgesics  OR  [new] Patient must be unable to use non-opioid or other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [21221] OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [21221] OxyContin and Novacodone modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

***TGA long-term pain indication: PBS restrictions in 2nd line setting***

* 1. Amend items:

**Listing 20: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 12mcg/hr patch):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| FENTANYL | 5265D | Transdermal patch 1.28 mg | 5 | 0 | Denpax | Alphapharm Pty Ltd |
|  | 5437E | Transdermal patch 2.063 mg | 5 | 0 | Dutran 12 | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Fenpatch 12 | Medis Pharma Pty Ltd |
|  | 8878G | Transdermal patch 2.1 mg | 5 | 0 | APO-Fentanyl | Apotex Pty Ltd |
|  |  |  |  | Durogesic 12 | Janssen-Cilag Pty Ltd |
|  |  |  |  | Fentanyl Sandoz | Sandoz Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13979] Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13979] Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

|  |  |
| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13979] Pharmaceutical benefits that have the form fentanyl 12 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 21: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 25mcg/hr patch):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| FENTANYL | 5277R | Transdermal patch 2.55 mg | 5 | 0 | Denpax | Alphapharm Pty Ltd |
|  | 5438F | Transdermal patch 4.125 mg | 5 | 0 | Dutran 25 | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Fenpatch 25 | Medis Pharma Pty Ltd |
|  | 8891Y | Transdermal patch 4.2 mg | 5 | 0 | APO-Fentanyl | Apotex Pty Ltd |
|  |  |  |  | Durogesic 25 | Janssen-Cilag Pty Ltd |
|  |  |  |  | Fentanyl Sandoz | Sandoz Pty Ltd |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13980] Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13980] Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13980] Pharmaceutical benefits that have the form fentanyl 25 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 22: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 50mcg/hr patch):**

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| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| FENTANYL | 5278T | Transdermal patch 5.10 mg | 5 | 0 | Denpax | Alphapharm Pty Ltd |
|  | 5439G | Transdermal patch 8.25 mg | 5 | 0 | Dutran 50 | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Fenpatch 50 | Medis Pharma Pty Ltd |
|  | 8892B | Transdermal patch 8.4 mg | 5 | 0 | APO-Fentanyl | Apotex Pty Ltd |
|  |  |  |  | Durogesic 50 | Janssen-Cilag Pty Ltd |
|  |  |  |  | Fentanyl Sandoz | Sandoz Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13981] Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13981] Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13981] Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 23: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 75mcg/hr patch):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| FENTANYL | 5279W | Transdermal patch 7.65 mg | 5 | 0 | Denpax | Alphapharm Pty Ltd |
|  | 5440H | Transdermal patch 12.375 mg | 5 | 0 | Dutran 75 | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Fenpatch 75 | Medis Pharma Pty Ltd |
|  | 8893C | Transdermal patch 12.6 mg | 5 | 0 | APO-Fentanyl | Apotex Pty Ltd |
|  |  |  |  | Durogesic 75 | Janssen-Cilag Pty Ltd |
|  |  |  |  | Fentanyl Sandoz | Sandoz Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13983] Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13983] Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13983] Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 24: Restriction for long-term pain TGA indication in 2nd line opioid setting on general schedule (fentanyl 100mcg/hr patch):**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| LI Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| FENTANYL | 5280X | Transdermal patch 10.20 mg | 5 | 0 | Denpax | Alphapharm Pty Ltd |
|  | 5441J | Transdermal patch 16.5 mg | 5 | 0 | Dutran 100 | Amneal Pharmaceuticals Pty Ltd |
|  |  |  |  | Fenpatch 100 | Medis Pharma Pty Ltd |
|  | 8894D | Transdermal patch 16.8 mg | 5 | 0 | APO-Fentanyl | Apotex Pty Ltd |
|  |  |  |  | Durogesic 100 | Janssen-Cilag Pty Ltd |
|  |  |  |  | Fentanyl Sandoz | Sandoz Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13984] Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| --- | --- |
| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13984] Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [13978] Fentanyl transdermal patches are not recommended in opioid naive patients with non-cancer pain because of a high incidence of adverse events in these patients. Patients with cancer pain may be initiated on the lowest strength patch (12 micrograms per hour).  [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [13984] Pharmaceutical benefits that have the form fentanyl 100 microgram/hour patch are equivalent for the purposes of substitution.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 25: Restriction for long-term pain TGA indication in 2nd line opioid setting (hydromorphone MR tablets):**

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| Legal Instrument Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| HYDROMORPHONE | 9407D | Tablet (modified release) containing hydromorphone hydrochloride 16 mg | 14 | 0 | Jurnista | Janssen-Cilag Pty Ltd |
|  | 9408E | Tablet (modified release) containing hydromorphone hydrochloride 32 mg | 14 | 0 | Jurnista | Janssen-Cilag Pty Ltd |
|  | 9299K | Tablet (modified release) containing hydromorphone hydrochloride 4 mg | 14 | 0 | Jurnista | Janssen-Cilag Pty Ltd |
|  | 9409F | Tablet (modified release) containing hydromorphone hydrochloride 64 mg | 14 | 0 | Jurnista | Janssen-Cilag Pty Ltd |
|  | 9406C | Tablet (modified release) containing hydromorphone hydrochloride 8 mg | 14 | 0 | Jurnista | Janssen-Cilag Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [new] Chronic severe pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.    [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.    [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not suitable for ‘as-required’ pain relief.    [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857  [Your capital city] |
| **Cautions:** | [6986] The risk of drug dependence is high. |

* 1. Amend items:

**Listing 26: Restriction for long-term pain TGA indication in 2nd line opioid setting (methadone injection and IR tablet):**

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| Legal Instrument Drug | Item Code | Legal Instrument Form | Max. Qty | No. Rpt | Brand Name | Responsible Person |
| METHADONE | 1606M | Injection containing methadone hydrochloride 10 mg in 1 mL | 5 | 0 | Physeptone | Aspen Pharma Pty Ltd |
|  | 1609Q | Tablet containing methadone hydrochloride 10 mg | 20 | 0 | Physeptone | Aspen Pharma Pty Ltd |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total duration of non-PBS and PBS subsidised opioid analgesic treatment is less than 12 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not recommended for use in ambulant patients.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857 |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months. |
| **Clinical criteria:** | [new] The condition must require daily, continuous, long term treatment  AND  [new] Patient must not be opioid naïve  AND  [18096] Patient must have cancer pain  OR  [new] Patient must have had or would have inadequate pain management with tolerated doses of non-opioid and other opioid analgesics  OR  [new] Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment:  (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not recommended for use in ambulant patients.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857 |
| **Cautions:** | [6986] The risk of drug dependence is high. |

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| **Category / Program:** | GENERAL – General Schedule (Code GE) |
| **Prescriber type:** | Dental Medical Practitioners Nurse practitioners Optometrists  Midwives |
| **PBS indication:** | [9729] Chronic severe disabling pain |
| **Restriction Level / Method:** | Unrestricted benefit  Restricted benefit  Authority Required – In Writing  Authority Required – Telephone/Electronic/Emergency  Streamlined |
| **Treatment phase:** | Continuing PBS treatment after 1 June 2020. |
| **Clinical criteria:** | [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. |
| **Prescriber instruction:** | [new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received initial authority approval and the total duration of non-PBS and PBS opioid analgesic treatment:  (i) is less than 12 months; or  (ii) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or  (iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or  (iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.  [new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.  Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats). |
| **Administrative advice:** | [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.  [new] This treatment is not recommended for use in ambulant patients.  [new] This treatment is not suitable for ‘as-required’ pain relief.  [7901] 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.  [new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)  Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.  Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:  Pharmaceutical Benefits Scheme  Reply Paid 9857 |
| **Cautions:** | [6986] The risk of drug dependence is high. |

1. <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2019-07/oxycodone-capsule-containing-oxycodone-hydrochloride-5-mg%3B> [↑](#footnote-ref-1)