11.03 TGA Prescription Opioid Regulatory Reforms

1 Purpose

1.1 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

2.1 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.

2.2 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.

2.3 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]).

3 Current situation

3.1 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.

3.2 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

[1] http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2019-07/oxycodone-capsule-containing-oxycodone-hydrochloride-5-mg%3B

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.
2. 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 naive 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).

Regulatory measures	TGA timing and remit under the *Therapeutic Goods Act 1989*
3. 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.
4. **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

4 Smaller pack sizes for immediate-release opioids

4.1 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.

4.2 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.

4.3 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).

4.4 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.

4.5 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	MQ[A]	DPMQ (as at 1 Dec 2019)	Tablets per blister in currently available pack size	TGA proposed new pack size[B]	Proposed smaller MQ[B]	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 30mL[D]	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.

4.6 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.

4.7 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 $1.0 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

4.8 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).

4.9 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.

4.10 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).

5 Narrower indications for fentanyl patches

5.1 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.

5.2 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.

5.3 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.

5.4 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).

5.5 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.

6 Revised indications for immediate- and modified-release opioids

6.1 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.

6.2 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.

6.3 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.

6.4 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.

7 Boxed warnings and class statements

7.1 The TGA advised that warnings and statements would be prominently displayed on the PIs and CMIs of all prescription opioid products registered in Australia.

7.2 The Secretariat proposed that the caution 'the risk of drug dependence is high' be applied consistently across all of the relevant listings.

8 PBAC Outcome

8.1 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.

8.2 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.

8.3 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.

8.4 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.

8.5 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.

8.6 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.

8.7 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".

8.8 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.

8.9 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.

8.10 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.

8.11 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.

8.12 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.

8.13 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.

8.14 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.

9 Recommended Listings

Contents

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

9.1 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

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.

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.

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.

9.2 Delete item: 8611F

9.3 Delete item: 8785J

9.4 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

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.

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.

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.

9.5 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

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.

9.6 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

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.

9.7 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 Code	Item	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

9.8 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.

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.

9.9 Amend item:

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

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

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.

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.

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.

9.10 Amend items:

Listing 8: 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	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

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.

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.

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.

9.11 Amend items:

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

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 MORPHINE SULFATE 10 mg/1 mL MEDSURGE	Pfizer Australia Pty Ltd Medsurge Healthcare Pty Ltd
	1645N	Injection containing morphine sulfate pentahydrate 15 mg in 1 mL	5	0	Hospira Pty Limited MORPHINE SULFATE 15 mg/1 mL MEDSURGE	Pfizer Australia Pty Ltd 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
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.

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.

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.

9.12 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.

9.13 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 MORPHINE SULFATE 15 mg/1 mL MEDSURGE	Pfizer Australia Pty Ltd Medsurge Healthcare Pty Ltd
	5170D	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

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

9.14 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

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.

9.15 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

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

9.16 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.

9.17 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

9.18 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

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.

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.

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.

9.19 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

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 [10096] 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.

9.20 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

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.

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.

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.

9.21 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):

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

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.

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.

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.

9.22 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):

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

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.

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.

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

9.23 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

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.

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.

9.24 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

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.

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.

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.

9.25 Amend items:

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

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

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.

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.

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.

9.26 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

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.

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 through 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.

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.

9.27 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

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.

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.

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.

9.28 Amend items:

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

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

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.

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 through 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.

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.

9.29 Amend items:

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

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

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.

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
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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.