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 Realth 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 meeting¹).

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

¹http://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

Re	gulatory 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, tramado!, 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 naïve patients.	6 months from Oct 2019 The TGA has existing powers to amend the indication for safety reasons. The innovator sponsor, Janssen-Cilag, is expected to complete its Product Information (PI) update by the end of 2019, with the three generic sponsors to follow soon after (generic sponsors are required to reflect safety information in the innovator PI).	

Regulatory measures	TGA timing and remit under the Therapeutic Goods Act 1989
Revised indications for immediate- and modified-release prescription opioids as follows.	12-24 months from Oct 2019 The TGA has existing powers to amend the PI on the grounds of safety.
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)	edom of Information Act 1987
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 table(s): [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 previde sufficient management of pain.	8000
4. Boxed warnings and class statements in the PI of all prescription opioids, and stronger warnings in the Consumer Medicines Information (CMI). Source: https://www.tra.gov.arvinoid-reforms-information-sponsors	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	5197Vi 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°	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 sneets) 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.

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- 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 \$3.0 million per year.

Table 3: Estimated net cost to PBS/RPBS as a result of new smaller (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.
- 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.

- 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):
 - 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.
- 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.

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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 Codalgin Forte Codapane Forte 500/30 Comfarol Forte Panadeine Forte Paracetamol/Codeine GH 500/30 Prodeine Forte	Apotex Pty Ltd Aphapharm Pty Ltd Alphapharm Pty Ltd Sandoz Pty Ltd sanofi-aventis Australia Pty Ltd Generic Health Pty Ltd sanofi-aventis Australia Pty Ltd
OXYCODONE	8501K	Capsule containing oxycodone hydrochloride 10 mg	20	0	OxyNorm Oxycodone BNM	Mundipharma Pty Limited Luminarie Pty Ltd
	8502L	Capsule containing oxycodone hydrochloride 20 mg	20	0	OxyNorm Oxycodone BNM	Mundipharma Pty Limited Luminarie Pty Ltd
	8464L	Capsule containing oxycodone hydrochloride	20	0	OxyNorm	Mundipharma Pty Limited
	8644Y	5 mg Oral solution containing oxycodene hydrochloride 1 mg per mL, 250 mL	1	0	Oxycodone BNM OxyNorm Liquid 1mg/mL	Luminarie Pty Ltd Mundipharma Pty Limited
	2622B	Tablet containing oxycodone hydrochloride 5 mg	20	0	Endone Mayne Pharma Oxycodone IR Oxycodone Aspen	Alphapharm Pty Ltd Mayne Pharma International Pty Ltd Alphapharm Pty Ltd
TRAMADOL	8455[3	Capsule containing tramadol hydrochloride 50 mg	20	0	APO-Tramadol Chem mart Tramadol	Apotex Pty Ltd Apotex Pty Ltd
TRAMADOL		30 mg			Terry White Chemists Tramadol Tramadol AMNEAL	Apotex Pty Ltd Amneal Pharmaceuticals Pty Ltd
					Tramadol AN	Amneal Pharmaceuticals Pty Ltd
					Tramadol SCP Tramadol Sandoz	Pharmacor Pty Limited Sandoz Pty Ltd
					Tramal	Seqirus (Australia) Pty Ltd
					Tramedo	Alphapharm Pty Ltd

					Zydol	Arrow Pharma Pty	
TRAMADOL	8582Q	Injection containing tramadol hydrochloride	5	0	Tramadol ACT	Ltd Juno Pharmaceuticals	
		100 mg in 2 mL			Tramadol AN	Pty Ltd Juno Pharmaceuticals	
					Tramadol Sandoz	Pty Ltd Sandoz Pty Ltd	
					Tramal 100	Seqirus (Australia)	
TRAMADOL	8843K	Oral drops containing	1	0	Tramal	Pty Ltd Seqirus (Australia)	
TTAMADOL	004310	tramadol hydrochloride	'	U	Hamai	Pty Ltd	
		100 mg per mL, 10 mL				, cò	
Category / Prog	ram:	GENERAL – General Sch	edule (Code	GE)		
Prescriber type:		☐ Dental ☑ Medical Prac			· (etrists	
Trescriber type.		Midwives		19 🖂	varse practitionersorient	iotrioto	
PBS indication:		[7861] Severe pain			corr.		
Restriction Leve	el / Method:	Unrestricted benefit			· IU		
		Restricted benefit					
		Authority Required – In Writing Authority Required – Telephone/Electronic/Emergency					
		Streamlined	eiepno	ne/⊑ie	ctronic/=mergency		
Treatment phas	e:		1 June	2020	where patient has been treat	ted with opioids	
_		for less than 12 months.		,0	·	·	
Clinical criteria:					nave inadequate pain manag	ement with	
		maximum tolerated doses	ot non	-opioid	danalgesics		
		OR OR					
			ble to	use no	n-opioid analgesics due to co	ontraindications	
Dan a saile sa isa sta		or intolerance.	1				
Prescriber instr	uctions:				m quantities and/or repeats u severe disabling pain associa		
					disabling pain where the total		
					esic treatment is less than 12		
	Inent was	[new] Authority requests e			tment duration up to 1 month		
	N. W.	requested though the Onli	ne PB	S Auth	orities system or by calling S	ervices Australia.	
	S)	Authority requests extending treatment duration beyond 1 month may be requested					
		through the Online PBS A			tem or in writing and must no		
C	,~	treatment duration exceed treatment and sufficient re			(quantity sufficient for up to	i montn	
		treatment and sumclent re	μσαιδ)	•			

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
his document was re	intolerance.
hie docum.	

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 nex 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.
	requested though the Online FBS Authorities system of 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.cov.au/organisations/health-
	professionals/services/medicare/hpos/services/request-authority-using-online-pbs- authorities-hpos)
	authornies-ripos
	Phone applications for increased maximum quantities/repeats may be made by
	calling 1600 888 333.
	Written authority applications for increased maximum quantities/repeats can be
	ploaded online through HPOS form upload or mailed to:
₹ [©]	Pharmaceutical Benefits Scheme
S	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
.5	
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 contirmed 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 curation up to 1 month may be requested though 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.servicesaus(ralia.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 cailing 1800 888 333.
Cautions	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: 8611F9.3 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 Instrum	ent Max.	Qty No. Rpt	Brand Name	Responsible Person
OXYCODONE	2481N	Suppository 3 (as pectinate)) mg 12	0	Proladone	Phebra Pty Ltd
Category / Prog	ram:	GENI	RAL – Genera	l Schedule (Code GE)	26
Prescriber type:			ental ⊠Medica dwives	l Practitione	rs ⊠Nurse practitio	ners Optometrists
PBS indication:		[7861] Severe pain			R
Restriction Leve	el / Method	⊠Re □Au □Au	restricted bene estricted benefit thority Required thority Required reamlined	d – In Writin	g ne/Electronic/Emerg	encyClation
Treatment phase	e:		PBS treatment ss than 12 mont		2020 where patiยาเ	has been treated with opioids
Clinical criteria:		[1809 OR	6] Patient must The treatment	have cance		following a major operative
		[new] maxir OR [new	num tolerate (c	oses of non e unable to	ould have inadequa opioid analgesics use non-opioid anal	te pain management with
Prescriber instru		[new]	Authorities for i tion must only n malignant neo	increased m be considere oplasia or ch	ed for severe disablir Ironic severe disablir	nd/or repeats under this ang pain associated with ang pain where the total gesic treatment is less than
is docus	nenta	[new] reque Austr	sted though the alia.	e Online PBS	S Authorities system	n up to 1 month may be or by calling Services
is 900cc		reque not po	sted through th	e Online PB ent duration	exceeding 3 months	nd 1 month may be n or in writing only and must (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
NO.	[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.
	Auditulia.
	Authority requests extending treatment duration beyond 1 month may be
	requested through the Online PES 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.servicesau@aiia.gov.au/organisations/health-
	professionals/se: vices/medicare/hpos/services/request-authority-using-online-pbs-
	authorities-npos)
	Phone applications for increased maximum quantities/repeats may be made by
	Calling 1800 888 333.
	Maria di si li si fi i di si di di si di s
(0)	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
.25	Pharmaceutical Benefits Scheme
n n	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
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 marie 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)
.(0	
°5°	Phone applications for increased maximum quantities/repeats may be made by
7,0	calling 1800 888 333.
X 3	
ocument was re	Written authority applications for increased maximum quantities/repeats can be
	uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme
, 00	Reply Paid 9857
Courties	[Your capital city] [6986] The risk of drug dependence is high.
Cautions:	[0300] The fisk of drug dependence is high.
7/1	•

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	20	0	Aspen Pharma Pty	Aspen Pharma
CODEINE WITH PARACETAMOL	3316M	hemihydrate 30 mg Tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg	20	0	Ltd APO- Paracetamol/Codeine 500/30 Codalgin Forte	Pty Ltd Apotex Pty Ltd Alphapharm Pty
					Codapane Forte 500/30 Comfarol Forte	Alphapharm Pty Ltd Sandoz Pty Ltd
				(Panadeine Forte Paracetamol/Codeine GI 500/30 Prodeine Forte	sanofi-aventis Australia Pty Ltd Generic Health Pty Ltd sanofi-aventis
OXYCODONE	5197M	Capsule containing oxycodone hydrochloride 10 mg	20	0	OxyNorm	Australia Pty Ltd Mundipharma Pty Limited
			.e20		Oxycodone BNM	Luminarie Pty Ltd
	5191F	Capsule containing oxycodone hydrochloride 5 mg	20	0	OxyNorm	Mundipharma Pty Limited
		ille			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	20	0	Endone	Alphapharm Pty Ltd
		nydrochioride 5 mg			Mayne Pharma Oxycodone IR	Mayne Pharma International Pty Ltd
		(e)e			Oxycodone Aspen	Alphapharm Pty Ltd
TRAMADOL	5232J	Capsule containing tramadol	20	0	APO-Tramadol	Apotex Pty Ltd
	. 5	nydrochloride 50 mg			Chem mart Tramadol	Apotex Pty Ltd
	Selle				Terry White Chemists Tramadol	Apotex Pty Ltd
This do	Shu,				Tramadol AMNEAL	Amneal Pharmaceuticals Pty Ltd
Nison					Tramadol AN	Amneal Pharmaceuticals
					Tramadol SCP	Pty Ltd Pharmacor Pty Limited
					Tramadol Sandoz	Sandoz Pty Ltd
					Tramal	Seqirus (Australia) Pty Ltd
					Tramedo	Alphapharm Pty Ltd
					Zydol	Arrow Pharma Pty Ltd

	Injection containing tramadol hydrochloride 100 mg in 2 mL	5	0	Tramadol ACT	Juno Pharmaceuticals Pty Ltd Juno
				Tramadol Sandoz	Pharmaceuticals Pty Ltd Sandoz Pty Ltd
				Halliauul Saliuuz	•
				Tramal 100	Seqirus
					(Australia) Pty Ltd
5150C	Oral drops containing tramadol	1	0	Tramal	Segirus
	hydrochloride 100 mg per mL, 10 mL				(Australia) Ftv Ltd
Category / Program:	GENERAL – General Schedule (Cod	le GE)			X
Prescriber type:	☐ Dental ☐ Medical Practitioners ☐	Nurse	practi	tioners Optometrists	200

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:	
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 ion-opioid analgesics OR [new] Patient must be unable to use non-opioid analgesics due to contraindications of intolerance.
Administrative advice:	[13808] Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.
Cautions:	
Cautions:	, eleass

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:

	Existing Ite Code	em Legal Instrument Form Max. No. Brand Name Res Qty Rpt	ponsible Persor
CODEINE	1214X		pen Pharma Pt
Category / Pro	ogram:	GENERAL – General Schedule (Code GE)	
Prescriber typ	De:	☐ Dental ☑ Medical Practitioners ☑ Nurse practitioners ☐ Optometrists ☐ Midwives	,
PBS indicatio	n:	[new] Cough	
Restriction Le	evel / Method:	☐ Unrestricted benefit ☐ Restricted benefit ☐ Authority Required – In Writing ☐ Authority Required – Telephone/Electronic/Emergency ☐ Streamlined	
Clinical criter	ia:	[new] Treatment must be for cough suppression.	
Cautions:		[6986] The risk of drug dependence is high.	
		eleased linde	
is de	CIMENT WE	[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		Legal Instrument Form	Max. Qty	No. Rpt	Brand Name	Responsible Person
HYDROMORPHONE	8421F	Injection containing hydromorphone hydrochloride 10	5	Ô	Dilaudid-HP HYDROMORPHONE	Mundipharma Pty Limited Juno Pharmaceuticals
		mg in 1 mL			JUNO-HP	Pty Ltd
	8420E	Injection containing hydromorphone	5	0	Dilaudid	Mundipharma Pty Limited
		hydrochloride 2 mg			HYDROMORPHONE	Juno Pharmaceuticals
	11467M	in 1 mL Oral liquid	1	0	JUNO Dilaudid	Pty Ltd Mundipharma Pty
	1 1407 W	containing	1	U	Dilaudiu	Limited
		hydromorphone			(77)	
		hydrochloride 1 mg				
	054414	per mL, 200 mL	00	^	D'I I'I	M I' I DI
	8541M	Tablet containing hydromorphone	20	0	Dilaudid	Mundipharma Pty Limited
		hydrochloride 2 mg				LITIILEU
	8542N	Tablet containing	20	0	Dilaudid	Mundipharma Pty
		hydromorphone		, (21	Limited
		hydrochloride 4 mg		Κ,		
	8543P	Tablet containing	20	\bigcirc 0	Dilaudid	Mundipharma Pty
		hydromorphone hydrochloride 8 mg	11/2			Limited
MORPHINE	2124T	Oral solution	(0)	0	Ordine 10	Mundipharma Pty
-		containing	<i>-</i>			Limited
		morphine				
		hydrochloride				
		trihydrare 10 mg per m', 200 mL				
	2122Q	Orai solution	1	0	Ordine 2	Mundipharma Pty
	- 1220	containing	•	·	014110 2	Limited
	S	morphine				
	No.	hydrochloride				
4	1	trihydrate 2 mg per				
20	2123R	mL, 200 mL Oral solution	1	0	Ordine 5	Mundipharma Pty
	212011	containing	'	U	Ordino 5	Limited
This docu		morphine				
90		hydrochloride				
:5		trihydrate 5 mg per				
XXII.	1646P	mL, 200 mL Tablet containing	20	0	Anamorph	Arrow Pharma Pty Ltd
*	10401	morphine sulfate	20	U	Anamorph	Allow I Haima I ty Lta
		pentahydrate 30				
		mg				
Cotomore / Description		OENEDAL O	' 0 '		(Cada CE)	1
Category / Program:		GENERAL – Ger			,	
Prescriber type:	□ Dental ☑ Medical Practitioners ☑ Nurse practitioners □ Optometrists					
PBS indication:		Midwives	nin			
FD3 IIIUICALION:		[7861] Severe pa	ail i			

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
Treatment phase.	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.
	Inoud Authority requests extending treatment duration up to 1 month may be
	[new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.
	requested though the online i bo rather these system et by canning our vious rather the.
	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
A	treatment and sufficient repeats).
Administrative advice:	[new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.
	Commencement of this medication.
	[new] Real time online opplications for increased maximum quantities/repeats may
	be made using the Online PBS Authorities system (see
	www.servicesausralia.gov.au/organisations/health-
	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-
	authorities-hoos)
	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
25	uploaded online through HPOS form upload or mailed to:
No	Pharmaceutical Benefits Scheme Reply Paid 9857
ant was	[Your capital city]
Cautions:	
	[6986] The risk of drug dependence is high.
	[6986] The risk of drug dependence is high.
Category / Program:	[6986] The risk of drug dependence is high.
outing 7, 1 regionin	
- N - 1	GENERAL – General Schedule (Code GE)
Prescriber type:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists Midwives
Prescriber type: PBS indication:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists
	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists Midwives
PBS indication:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists Midwives [7861] Severe pain Unrestricted benefit Restricted benefit
PBS indication:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists Midwives [7861] Severe pain Unrestricted benefit Restricted benefit Authority Required – In Writing
PBS indication:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Doptometrists Midwives [7861] Severe pain Unrestricted benefit Restricted benefit Authority Required – In Writing Authority Required – Telephone/Electronic/Emergency
PBS indication:	GENERAL – General Schedule (Code GE) Dental Medical Practitioners Nurse practitioners Optometrists Midwives [7861] Severe pain Unrestricted benefit Restricted benefit Authority Required – In Writing

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 commercement of this medication.
, Mas re	[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)
SIMENT	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
rhis document was re	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
Treatment phase:	Streamlined 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 curation 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 opicid 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.
	1.00
	[new] Palliative care nurses may conduct annual review under this item for the treatment of palliative care nations 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 reatment and sufficient repeats).
Administrative advice:	[new] Consider consultation with a multidisciplinary pain service prior to, or after
S	commencement of this medication.
18.3	[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-
illi	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-
Chi	authorities-hpos)
90	Phone applications for increased maximum quantities/repeats may be made by
Administrative advice:	calling 1800 888 333.
	Weitten suth site and in the facility of the second
*	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
On the second	[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	20	0	Sevredol	Mundipharma	
		sulfate pentahydrate 10 mg				Pty Limited	
	8670H	Tablet containing morphine	20	0	Sevredol	Mundipharma	
		sulfate pentahydrate 20 mg				Pty Limited	
						,00	
Category / Program:		GENERAL – General Schedule	(Code GE)				
Prescriber type:		☐ Dental ☐ Medical Practition	ers 🛮 Nurse	e practitio	ners Optometr	ists	
		Midwives				,	
PBS indication:		[New] Cancer pain			ilo.		
Restriction Level / N	lethod:	Unrestricted benefit			0.		
		Restricted benefit					
		Authority Required – In Writi	ng		<i>ξ</i> Ο'		
		Authority Required – Telepho	one/Electror	nic/Emerg	ency		
		Streamlined		<u> </u>			
Treatment phase:		Initial PBS treatment after 1 Jur	e 2020 whe	re patient	has been treated	with opioids	
		for less than 12 months.					
Clinical criteria:		[18096] Patient must have cand	er pain				
		AND	.00				
		AND					
		Inewl Patient must have had or	would have	inadequa	te nain managem	ent with	
		[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-op	ioid and o	ther opioid analge	esics due to	
		contraindications or intolerance					
Prescriber instruction	ons:	[new] Authorities for increased r	maximum qu	iantities a	nd/or repeats und	er this	
		restriction must only be conside					
		total ouration of non-PBS and P	BS subsidis	ed opioid	analgesic treatme	ent is less	
		theri 12 months.					
	C	[new] Authority requests extending treatment duration up to 1 month may be					
	40	requested though the Online PBS Authorities system or by calling Services					
	VI.	Australia.					
~(S	Authority requests extending tre	atment dura	ation bevo	nd 1 month may h	oe	
90chWeyt Mas		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					
700		month treatment and sufficient repeats).					
			1 1.				

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			
	<u></u> ∐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			
rreatment phase.	for more than 12 months.			
01: 1 1: 1:				
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			
Masic	OR			
[new] Patient must be unable to use non-opioid and other opioid analgesics				
, n	contraindications or intolerance.			
<u>_</u>	Contraindications of 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.
	Francis Authorita annual and a discontinuous description of the descri
	[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 chine 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)
	auticules-ripos)
	Fhone applications for increased maximum quantities/repeats may be made by
(0)	calling 1800 888 333.
inent was le	Written authority applications for increased maximum quantities/repeats can be
* 7	uploaded online through HPOS form upload or mailed to:
S.C.	Pharmaceutical Benefits Scheme
	Reply Paid 9857 [Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
700	
Caregory / 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.

Inew Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabiling 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 pai management review due to their clinical condition; or (iii) exceeds 12 months and the palliative care patient is unable to have annual pai 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 palliative care nurse practitioner in the past 12 months, but is planned in the next 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 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 month treatment and sufficient repeats). [new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this inedication. [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/request-authority-using-online-pbs authorities-hops) Phone applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharm	Clinical criteria:	[new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.
(ii) exceeds 12 months and the palliative care patient is unable to have annual pai 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 (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 bean confirmed through consultation with the patient by another medical practitioner or palliative care nurse practitioner in the past 12 months, but is planned in the next 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 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)	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
(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 of (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 palliative care nurse practitioner in the past 12 months, but is planned in the next is 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 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)		(ii) exceeds 12 months and the palliative care patient is unable to have annual pain
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 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.scrvicesaustralia.gov.au/organisations/health-profecsionals/services/medicare/hpos/services/request-authority-using-online-pbs authorities-hpos)		(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
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 month treatment and sufficient repeats). [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)		
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 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)		requested though the Online PBS Authorities system or by calling Services
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)		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
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)	Administrative advice:	
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]		professionals/services/medicare/hpos/services/request-authority-using-online-pbs-
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!	125,0	
[Your capital city]	INGUIN NO	uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme
Cautions: [6986] The risk of drug dependence is high.	Cautions	[Your capital city]

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 Pharma Couticals Pty Ltd
	10869C	Injection containing morphine hydrochloride trihydrate 50 mg in 5 mL	5	0	Morphine Juno	Juno Pinarmaceuticals Pty Ltd
	1647Q	Injection containing morphine sulfate pentahydrate 30 mg in 1 mL	5	0	Hospira Pty Limited MCRPHINE 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 man 12 months.
Clinical criteria:	[newi] Patient must have had or would have inadequate pain management with
	maximum tolerated doses of non-opioid and other opioid analgesics
4	
This document was	OR
4.0.	
	[new] Patient must be unable to use non-opioid and other opioid analgesics due to
	contraindications or intolerance
. No	OD
c))	OR
100	Inquil The treetment must be part of are energing care
0.0	[new] The treatment must be part of pre-operative care
i S	OR
XXI.	OIL
	[new] The treatment must be used as an analgesic adjunct in general anaesthesia.
	The first indication must be used as an analysis adjunct in general anaestnesia.

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
.0	Midwives
PBS indication:	[7861] Severe pain
Restriction Level / Method	Unrestricted benefit
* 74	Restricted benefit
	Authority Required – In Writing
20	Authority Required – Telephone/Electronic/Emergency
	Streamlined
Treatment obase:	Initial PBS treatment after 1 June 2020 where patient has been treated with opioids
20	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 necessary; 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.
, Most	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.
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]

Prescriber type: □ Dental □ Medical Practitioners □ Nurse practitioners □ Optometrists □ Midwives PBS indication: T861] Severe pain Restriction Level / Method: Unrestricted benefit □ Authority Required — In Writing □ Authority Required — Telephone/Electronic/Emergency □ Streamlined Treatment phase: Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with his form of this drug for this condition after 1 June 2020 Prescriber instructions: Inew] Authorities for increased maximum quantities and/or replace must only be considered where the patient has received initial authority approval for: (i) severe disabling pain associated with malignant neoplasis, or (ii) chronic severe disabling pain awhere the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months (or (iii) palliative care patients with chronic severe tisabling 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 managemath 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 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 exceeds 12 months prior to 1 June 2020 and the patient scinical 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; or (v) chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months. Inew] Palliative care nurses may conduct annual review under this item for the f	Cautions:	[6986] The risk of drug dependence is high.
Prescriber type: □Dental ☑Medical Practitioners ☑Nurse practitioners ☑Optometrists □Midwives PBS indication: Restriction Level / Method: □Unrestricted benefit ☑Restricted benefit □Authority Required – In Writing □Authority Required – Telephone/Electronic/Emergency ☑Streamlined Continuing PBS treatment after 1 June 2020 Prescriber instructions: □Dental ☑Authority Required – Telephone/Electronic/Emergency ☑Streamlined Continuing PBS treatment after 1 June 2020 Prescriber instructions: □Dental ☑Authority Required – Telephone/Electronic/Emergency ☑Streamlined □Dental ☑Dental ②Electronic/Emergency ☑Streamlined □Dental ☑Dental ②Electronic/Emergency ☑Streamlined □Dental ☑Dental ②Electronic/Emergency ☑Streamlined □Dental ②Electronic/Emergency ☑Streamlined □Dental ②Electronic/Emergency □Dental ③Electronic/Emergency □Dental ③Elect	Catamany / Drammany	CENEDAL Caparal Sahadula (Cada CE)
Midwives Restriction Level / Method:	Category / Program:	, ,
Restriction Level / Method: Unrestricted benefit Authority Required – In Writing Authority Required – Telephone/Electronic/Emergency Streamlined Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with his form of this drug for this condition after 1 June 2020. [new] Authorities for increased maximum quantities and/or repeats must only be considered where the patient has received initial authority by roval 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 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 exceeds 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid 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 freatment of palliative care patients only.	Prescriber type:	
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Authority Required – In Writing Authority Required – Telephone/Electronic/Emergency Streamlined Treatment phase: Continuing PBS treatment after 1 June 2020 Patient must have previously received PBS-subsidised treatment with his form of this drug for this condition after 1 June 2020. [new] Authorities for increased maximum quantities and/or received 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 been confirmed through consultation with 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 or a palliative care nurse 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.	Restriction Level / Method:	
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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 freatment of palliative care patients only.		continuing opioid treatment has been confirmed through consultation with the nationt
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 freatment of palliative care patients only.		
(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 freatment of palliative care patients only.		. //
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 freatment of palliative care patients only.		
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.		
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] Palliative care nurses may conduct annual review under this item for the reatment of palliative care patients only.		
treatment of palliative care patients only.		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).		treatment of palliative care patients only.
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).		Inew Authority requests extending treatment duration up to 1 month may be
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).	Mas	
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).		Authority requests extending treatment duration beyond 1 month may be requested
treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).		
treatment and sufficient repeats).		
	<u> </u>	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
Cautions:	[Your capital city] [6986] The risk of drug dependence is high.
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	inderther
Nas re	[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 Pharmaceut Pty Ltd	ticals
	1644M	Injection containing morphine sulfate pentahydrate 10 mg in 1 mL	5	0	Hospira Pty Limited MORPHINE SULFATE 10 mg/1 mL MEDSURGE Pfizer Austra Ltd Medsurge Healthcare	100
	1645N	Injection containing morphine sulfate pentahydrate 15 mg in 1 mL	5	0	Hospira Pty Limited MORPHINE SULFATE Healthcare I Torg/1 mL MEDSURGE	•

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
Restriction Level / Metriod.	Restricted benefit
	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
	Streamlined
Treatment phase:	Initial FBS treatment after 1 June 2020 where patient has been treated with opioids
Treatment phase.	for less than 12 months.
Oliminal suitavia:	
Clinical criteria:	[new] Patient must have had or would have inadequate pain management with
\$	maximum tolerated doses of non-opioid and other opioid analgesics
G	OR
100	ON
, Il	[new] Patient must be unable to use non-opioid and other opioid analgesics due to
	contraindications or intolerance
\O\	Contramidications of intolerance
	OR
CO	
200	[new] The treatment must be part of pre-operative care
. 6	Front standards barrer big sharange and
this document was re	OR
	[new] The treatment must be used as an analgesic adjunct in general anaesthesia.
	1 Promiting the statement made to adda as an analysis adjunct in general analysis and

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/mi/ 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/healtiprofessionals/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
.25	Midwives
PBS indication:	[7861] Severe pain
Restriction Level / Method:	Unrestricted benefit
	Restricted benefit
	☐Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
20	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 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 neopiasia; 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.
	20
	[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.
.0	Authority requests extending treatment duration beyond 1 month may be requested
125	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
1 12	treatment and sufficient repeats).

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 ber efit
	⊠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.
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Duna and have been also also also also also also also also	Frank A. Harris and A. Harris
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 1.2
	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 curation up to 1 month may be
	requested though the Online PBS Authorities system or by calling Services Australia.
	Authority requests extending treatment curation 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 reneats).
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
	commercement of this medication.
	[new] Real time online applications for increased maximum quantities/repeats may
	Ge made using the Online PBS Authorities system (see
40	www.servicesaustralia.gov.au/organisations/health-
6	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-
10.3	authorities-hpos)
* 21	
	Phone applications for increased maximum quantities/repeats may be made by
This document was re	calling 1800 888 333.
-CV	Written authority applications for increased maximum quantities/repeats can be
70-	uploaded online through HPOS form upload or mailed to:
. 60	Pharmaceutical Benefits Scheme
Wiles	Reply Paid 9857
	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
	<u> </u>

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	1	0	Dilaudid	Mundipharma
		hydrochloride 1 mg per mL, 200 mL				Pty Limited
	5115F	Tablet containing hydromorphone	20	0	Dilaudid	Mundipharma
		hydrochloride 2 mg				Pty Li nited
	5116G	Tablet containing hydromorphone	20	0	Dilaudid	Mundipharma
		hydrochloride 4 mg				Pty Limited
	5117H	Tablet containing hydromorphone	20	0	Dilaudid	Mundipharma
		hydrochloride 8 mg				Pty Limited
MORPHINE	5239R	Oral solution containing morphine	1	0	Ordine 10	Mundipharma
		hydrochloride trihydrate 10 mg per mL, 200 mL			×,0,	Pty Limited
	5237P	Oral solution containing morphine	1	0	Ordine 2	Mundipharma
		hydrochloride trihydrate 2 mg per mL, 200 mL				Pty Limited
	5238Q	Oral solution containing morphine	1	0	Ordine 5	Mundipharma
		hydrochloride trihydrate 5 mg per mL, 200 mL		10		Pty Limited
	5163R	Tablet containing morphine sulfate	20	0	Anamorph	Arrow Pharma
		pentahydrate 30 mg),		Pty Ltd
			0			

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☐ Medical Practitioners ☐ Notes 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 colerated 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 MEDS/JRGE	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:	
PBS indication:	[7861] Severe pain
Restriction Level / Method: Clinical criteria:	☐ 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
Clinical criteria:	[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.

This document was released under the Feedom of Information Act, 1989.

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 CODEINE WITH PARACETAMOL	1214X 1215Y	Tablet containing codeine phosphate hemihydrate 30 mg Tablet containing codeine phosphate hemihydrate 30 mg	10 10	0	Aspen Pharma Pty Ltd APO- Paracetamol/Codeine	Aspen Pharma Pty Ltd Apotex Pty Ltd
		with paracetamol 500 mg			500/30 Codalgin Forte	Alphapharm Pty Ltd
					Codapane Forte 500/30 Comfarol Forte	Alphapharm Pty Ltd
					Panadeine Forte	Sandoz Pty Ltd sanofi-aventis
					Paracetamol/Codeine GH 500/30	Australia Pty Ltd Generic Health Pty Ltd
OXYCODONE	8501K	Capsule containing oxycodone	10		Prodeine Forte OxyNorm	sanofi-aventis Australia Pty Ltd Mundipharma Pty
		hydrochloride 10 mg	4 8	690,	Oxycodone BNM	Limited Luminarie Pty Ltd
	8464L	Capsule containing oxycodone hydrochloride 5 mg	210	0	OxyNorm	Mundipharma Pty Limited
		No.			Oxycodone BNM	Luminarie Pty Ltd
	8644Y	Oral solution containing oxycodone hydrochloride i mg per mL, 250 mL	1	0	OxyNorm Liquid 1mg/mL	Mundipharma Pty Limited
	2622B	Tablet containing oxycodone	10	0	Endone	Alphapharm Pty Ltd
		hydrochloride 5 mg			Mayne Pharma Oxycodone IR Oxycodone Aspen	Mayne Pharma International Pty Ltd Alphapharm Pty Ltd
TRAMADOL	8455B	Capsule containing tramadol	10	0	APO-Tramadol	Apotex Pty Ltd
		nydrochloride 50 mg			Chem mart Tramadol	Apotex Pty Ltd
	N. N.	Capsule containing tramadol nydrochloride 50 mg			Terry White Chemists Tramadol	Apotex Pty Ltd
-	ILLE,				Tramadol AMNEAL	Amneal Pharmaceuticals Pty Ltd
This doc					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
	00.4017		,		Zydol	Arrow Pharma Pty Ltd
	8843K	Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL	1	0	Tramal	Seqirus (Australia) Pty Ltd

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.
Cautions:	[6986] The risk of drug dependence is high.
	[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	10	0	APO- Paracetamol/Codeine 500/30	Apotex Pty Ltd
		500 mg			Codalgin Forte	Alphapharm Pty Ltd
					Codapane Forte 500/30 Comfarol Forte	Alphapnarm Pty Ltd Sandoz Pty Ltd
					Panadeine Forte	sanofi-aventis
					i anademe i orte	Australia Pty Ltd
					Paracetamol/Codeine	Generic Health
					GH 500/30 Prod∈in∋ Forte	Pty Ltd sanofi-aventis
					2	Australia Pty Ltd
OXYCODONE	5197M	Capsule containing oxycodone hydrochloride	10	0	CxyNorm	Mundipharma Pty Limited
		10 mg			Oxycodone BNM	Luminarie Pty Ltd
	5191F	Capsule containing oxycodone hydrochloride	10	0	OxyNorm	Mundipharma Pty Limited
		5 mg			Oxycodone BNM	Luminarie Pty Ltd
	5190E	Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL	0 1	0	OxyNorm Liquid 1mg/mL	Mundipharma Pty Limited
	5195K	Tablet containing oxycodone hydrochloride	10	0	Endone	Alphapharm Pty Ltd
		5 mg			Mayne Pharma Oxycodone IR	Mayne Pharma International Pty Ltd
	. 1	105			Oxycodone Aspen	Alphapharm Pty Ltd
TRAMADOL	52321	Capsule containing	10	0	APO-Tramadol	Apotex Pty Ltd
	SI.	tramadol hydrochloride 50 mg			Chem mart Tramadol	•
	<i>'</i> C'.	3			Terry White Chemists Tramadol	Apotex Pty Ltd
TRAMADOL					Tramadol AMNEAL	Amneal Pharmaceuticals Pty Ltd
YVII.					Tramadol AN	Amneal Pharmaceuticals
					Tramadol SCP	Pty Ltd Pharmacor Pty Limited
					Tramadol Sandoz	Sandoz Pty Ltd
					Tramal	Seqirus (Australia) Pty Ltd
					Tramedo	Alphapharm Pty Ltd

Oral drops containing tramadol hydrochloride 100 mg per mL, 10 mL

5150C

Zydol Arrow Pharma Pty
Ltd

1 0 Tramal Seqirus (Australia)
Pty Ltd

Category / Program:
Prescriber type:
PBS indication:
Restriction Level / Method:
Clinical criteria:
Administrative advice:
Cautions:
Cautions:

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	Mundioharma 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	1	0	Ordine 10	Mundipharma Pty Limited
	2122Q	per mL, 200 mL Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL	1	0, 18,	Ordine 2	Mundipharma Pty Limited
	2123R	Oral solution containing morphine hydrochloride trihydrate 5 mg per	egolf.	0	Ordine 5	Mundipharma Pty Limited
	1646P	mL, 200 mL Tablet containing morphine sulfate pentahydrate 30 mg	10	0	Anamorph	Arrow Pharma Pty Ltd
Category / Program:		GENERAL – General Schedule (Code GE)			
Prescriber type:		☐ Dental ☑ Micdical Practitione ☐ Midwives	rs ⊠Nurse	practition	ers Optometr	sts
PBS indication:		[7861] Severe pain				
Restriction Level / Me	ethod:	☐ In estricted benefit ☐ Restricted benefit ☐ Authority Required – In Writin ☐ Authority Required – Telepho ☐ Streamlined		ic/Emerge	ency	
Clinical criteria:	× 190	[new] The treatment must be for	short term t	herapy of	acute severe pai	n
a ci		AND				
This docum		[new] Patient must have had or we maximum tolerated doses of non OR [new] Patient must be unable to contraindications or intolerance.	-opioid and	other opio	oid analgesics	
Administrative advice	e:	[7606] No increase in the maximum [7607] No increase in the maximum				
Cautions:		[6986] The risk of drug depender				

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 Fty Limited
	5116G	Tablet containing hydromorphone hydrochloride 4 mg	10	0	Dilaudid	Mundipharma Pty Limited
	5117H	Tablet containing hydromorphone hydrochloride 8 mg	10	0	Dilaudid	Nicodipharma 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 0	Ordine 5	Mundipharma Pty Limited
	5163R	Tablet containing morphine sulfate pentahydrate 30 mg	6010	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
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
Administrative advice:	contraindications or intolerance. [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	Qty	lo. Rpt	Brand Name	Responsible Person
BUPRENORPHINE	8866P	Transdermal patch 10 mg	2	0	Bupredermal	Apotex Ptv Ltd
					Buprenorphine Sandoz Norspan	Sandoz Pty Ltd 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
				٧,	Suprenorphine Sandoz	Sandoz Pty Ltd
				0,	Norspan	Mundipharma Pty Limited
	10756D	Transdermal patch 25 mg	2	0	Norspan	Mundipharma Pty Limited
	10755C	Transdermal patch 30 mg	CO	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
		ingle.			Buprenorphine Sandoz	Sandoz Pty Ltd
		690			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
CHI	8494C	Capsule containing morphine sulfate pentahydrate 120 mg (controlled release)	14	0	MS Mono	Mundipharma Pty Limited
This goo	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	28	0	Kapanol	Mayne Pharma International Pty Ltd
	8492Y	pellets) 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 80017	0	MORPHINE MR APOTEX MS Contin	Apotex Pty Ltd Mundipharma Pty Limited
	<	100		Momex SR 10	Arrow Pharma
	sulfate pentahydrate 10 mg (controlled release)			Morphine MR AN	Pty Ltd Amneal Pharmaceuticals Pty Ltd
	INDE			Morphine MR Mylan	Alphapharm Pty Ltd
1656E	Tablet containing morphine sulfate pentahydrate 100 mg	28	0	MORPHINE MR APOTEX	Apotex Pty Ltd
	(controlled elease)			MS Contin	Mundipharma Pty Limited
	5			Momex SR 100	Arrow Pharma Pty Ltd
Ment W	D			Morphine MR AN	Amneal Pharmaceuticals Pty Ltd
Me,				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	28	0	MORPHINE MR APOTEX	Apotex Pty Ltd
	(controlled release)			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 MS Contin	Apotex Pty Ltd Mundipharma
		(controlled release)				Pty Limited
					Momex SR 60	Arrow Pharma Pty Ltd
					Morphine MR AN	Amneal Pharmaceuticals
					Morphine MR	Pty Ltd Alphapharm Pty
					Mylan	Ltd
OXYCODONE	8934F	Tablet (controlled release)	28	0	Targin 10/5mg	Mundipharma
WITH NALOXONE		containing oxycodone				Pty Limited
		hydrochloride 10 mg with naloxone hydrochloride 5 mg			10/1	
	10757E	Tablet (controlled release)	28	0	Targin 15/7.5mg	Mundipharma
	101012	containing oxycodone	20	Ū	raigin is isomy	Pty Limited
		hydrochloride 15 mg with			(O)	,
		naloxone hydrochloride 7.5 mg				
	10776E	Tablet (controlled release)	28	Ĉ	Targin 2.5/1.25	Mundipharma
		containing oxycodone	_	O	mg	Pty Limited
		hydrochloride 2.5 mg with				
	8935G	naloxone hydrochloride 1.25 mg	28	Λ	Targin 20/10mg	Mundinharma
	0933G	Tablet (controlled release) containing oxycodone	20)	0	rargin 20/10mg	Mundipharma Pty Limited
		hydrochloride 20 mg with				r ty Lillilleu
		naloxone hydrochloride 10 mg				
	10758F	Tablet (controlled release)	28	0	Targin 30/15 mg	Mundipharma
		containing oxycodone			0 0	Pty Limited
		hydrochloride 30 mg with				•
		naloxone hydrochloride 15 mg				
	8936H	Tablet (controlled release)	28	0	Targin 40/20mg	Mundipharma
		containing oxyccdone				Pty Limited
		hydrochloride 40 mg with				
	8000C	naloxcons hydrochloride 20 mg Table*(controlled release)	28	0	Targin 5/2.5mg	Mundipharma
	00000	containing oxycodone	20	U	raigin 3/2.5mg	Pty Limited
	,(hydrochloride 5 mg with naloxone				r ty Emiliou
	" N	hydrochloride 2.5 mg				
TADENTADOL	11102H	Tablet (controlled release)	28	0	Targin 60/30	Mundipharma
	ï,	containing oxycodone				Pty Limited
		hydrochloride 60 mg with				
CO	11111T	naloxone hydrochloride 30 mg Tablet (controlled release)	20	٥	Targin 80/40	Mundinharma
90	111111	containing oxycodone	28	0	rargin 60/40	Mundipharma Pty Limited
:5		hydrochloride 80 mg with				r ty Emiliou
YIV.		naloxone hydrochloride 40 mg				
TAPENTADOL	10094G	Tablet (modified release) 100 mg	28	0	Palexia SR	Seqirus
		(as hydrochloride)				(Australia) Pty
	4040011	- /		•	D	Ltd
	10100N	Tablet (modified release) 150 mg	28	0	Palexia SR	Seqirus
		(as hydrochloride)				(Australia) Pty Ltd
	10091D	Tablet (modified release) 200 mg	28	0	Palexia SR	Segirus
	100010	(as hydrochloride)	20	J	. alonia OIX	(Australia) Pty
						Ltd

	10092E	Tablet (modified release) 250 mg (as hydrochloride)	28	0	Palexia SR	Seqirus (Australia) Pty
	10096J	Tablet (modified release) 50 mg (as hydrochloride)	28	0	Palexia SR	Ltd Seqirus (Australia) Pty
TRAMADOL	8523N	Tablet (sustained release)	20	0	APO-Tramadol	Ltd Apotex Pty Ltd
		containing tramadol hydrochloride 100 mg			SR Chem mart Tramadol SR	Apotex Pty Ltd
					Terry White Chemists	Apotex Pty Ltd
					Tramadol SR Tramadol AN SR	Amneal Pharmaceuticals
					Tramadol SR	Pty Ltd Generic Health
					generichealth Tramado! Sandoz SR	Pty Ltd Sandoz Pty Ltd
				ç	Tramai SR 100	Seqirus (Australia) Pty Ltd
			k os doin	0	Tramedo SR	Alphapharm Pty Ltd
			6901		Zydol SR 100	Arrow Pharma Pty Ltd
	8524P	Tablet (sustained release)	2 0	0	APO-Tramadol SR	Apotex Pty Ltd
		150 mg			Chem mart Tramadol SR	Apotex Pty Ltd
		del			Terry White Chemists	Apotex Pty Ltd
					Tramadol SR Tramadol AN SR	Amneal
		2560			Hamadol AN SK	Pharmaceuticals Pty Ltd
		200			Tramadol SR	Generic Health
		25			generichealth Tramadol Sandoz SR	Pty Ltd Sandoz Pty Ltd
	on't w	Tablet (sustained release) containing tramadol hydrochloride 150 mg Tablet (sustained release) containing tramadol hydrochloride 200 mg			Tramal SR 150	Seqirus (Australia) Pty Ltd
راح					Tramedo SR	Alphapharm Pty Ltd
900					Zydol SR 150	Arrow Pharma Pty Ltd
This	8525Q	Tablet (sustained release)	20	0	APO-Tramadol SR	Apotex Pty Ltd
		200 mg			Chem mart Tramadol SR	Apotex Pty Ltd
					Terry White Chemists	Apotex Pty Ltd
					Tramadol SR Tramadol AN SR	Amneal Pharmaceuticals Pty Ltd
					Tramadol SR generichealth	Generic Health Pty Ltd

Tramadol Sandoz Sandoz Pty Ltd SR Seqirus (Australia) Pty Tramal SR 200 Ĺtd Alphapharm Pty Ltd Tramedo SR Arrow Pharma Zydol SR 200 Pty Ltd Seqirus (Australia) Pty 2527B Tablet (sustained release) 20 Tramal SR 50 containing tramadol hydrochloride 50 mg Ètd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☑ Medical Practitioners ☑ Nurse practitioners ☐ Optometris\s
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 whore 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
Prescriber instruction:	contraindications or intolerance. [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.
document was	[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
is 300°	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 ber efit □ Restricted ber efit □ 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
Clinical criteria:	[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.
	past 12 months, but is planned in the next o 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 amonth 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
A1	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.servicescustralia.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
10.3	uploaded online through HPOS form upload or mailed to:
* 7	Pharmaceutical Benefits Scheme
OSLIT MOS	Reply Paid 9857
Cautions:	[Your capital city] [6986] The risk of drug dependence is high.
Cautions.	[0300] The fisk of drug dependence is high.
300	
Category / Program:	GENERAL – General Schedule (Code GE)
Frescriber 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 curation 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-
5	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)
in in the second	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
is document was	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
4012	[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	Murdipharma Pty Limited

	10
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
	[COCC] Detient must be us consequed.
	[18996] Patient must have cancer pain
.0	[new] Patient must have had or would have inadequate pain management with
	maximum tolerated doses of non-opioid or other opioid analgesics
100	OR
Nasi	[new] Patient must be unable to use non-opioid or other opioid analgesics due to
	contraindications or intolerance.
Administrative addice:	[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.
C).	
20	[new] This treatment is not suitable for 'as-required' pain relief.
:5	77004104 10 14 14 5 14 14 14 14 14 14 14 14 14 14 14 14 14
	[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 ☐ Norse 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
IMERIT Was re	[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
CHILL	[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 ber efit □ Restricted ber efit □ 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
Clinical criteria:	[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 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.services.custralia.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.
5	Written authority applications for increased maximum quantities/repeats can be
No	uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme Reply Paid 9857
CELT MOS,	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
100	
Category / Program:	GENERAL – General Schedule (Code GE)
Frescriber type:	☐Dental ☐Medical Practitioners ☐Nurse practitioners ☐Optometrists
PBS indication:	Midwives [9729] Chronic severe disabling pain
Restriction Level / Method:	Unrestricted benefit Restricted benefit
	☐ Authority Required – In Writing
T ()	Streamlined
Treatment phase:	Continuing PBS treatment after 1 June 2020.

Clinical criteria:	[new] Patient must have previously received PBS-subsidised treatment with this form
Prescriber instruction:	of this drug for this condition after 1 June 2020. [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.
	0.
	Authority requests extending treatment curation 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.
	*//6
	[7901] Shared Care Model: For prescribing by nurse practitioners where care of a
	patient is shared to ween 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-
and the state of t	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)
10.3	dulionido ripody
, C	Phone applications for increased maximum quantities/repeats may be made by
is document was re	calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be
Ci))	uploaded online through HPOS form upload or mailed to:
200	Pharmaceutical Benefits Scheme
.60	Reply Paid 9857
401	[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

LI Drug Item Legal Insti Code		rument 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 cor	staining oxycodone ride 30 mg (controlled	28	0	OxyContin	Mundipharma Pty Limited
Category / Pro	gram:		GENERAL – General	Schedule	e (Code (GE)	~~~
Prescriber type	e:		□ 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 can	cer pain		
			[new] Patient must ha maximum tolerated do OR	oses of no	on-opioid	or other opioid a	·
			[new] Patient must be	unable to	o use no	n-opioid or other	opioid analgesics due to

contraindications or intolerance.

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).

[new] Authorities for increased maximum quantities and/or repeats under this restriction will be granted only for chronic severe disabling pain where the total

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 cuantities/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 kigh.

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☑ Medical Practitioners ☑ Nurse practitioners ☐ Optometrists
	Midwives
PBS indication:	[new] Chronic se 'ere 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
S	for more than 12 months.
Clinical criteria:	[new] The condition must require daily, continuous, long term opioid treatment
Clinical criteria:	AND
	[18096] Patient must have cancer pain
C).	OR
20	[new] Patient must have had or would have inadequate pain management with
. 6	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.
	contraint december of interestation

Prescriber instruction:	[new] Authorities for increased maximum quantities and/or repeats must only be
Prescriber instruction.	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.
	past 12 months, but is planned in the next 5 months.
	[new] Palliative care nurses may conduct annual review under this item for the
	treatment of palliative care patients only.
	treatment of paliative 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.
	requestion along it the crimine is not required ayatem of by carrier between Australia.
	Authority requests extending treatment duration beyond 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.
	"We
	[10909] OxyContin modified release tablets are intended to be crush-deterrent and
	to reduce the rapi 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.se.vicesaustralia.gov.au/organisations/health-
	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-
	authorities-hpos)
1	Dhana applications for increased maximum swantitical repeats may be made by
25	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
No.	Calling 1000 000 555.
A. T	Written authority applications for increased maximum quantities/repeats can be
0	uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme
ci)),	Reply Paid 9857
OCIMENT NOSTE	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
3	

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 a mual pain management review due to their clinical condition; or (iii) exceeds 12 months and the patient's clinical need for continuing epioid 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 entry.
	[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.
, Was id	[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.
nent	[10909] OxyContin modified release tablets are intended to be crush-deterrent and to reduce the rapid release of oxycodone upon accidental or intentional misuse.
This document was re	[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.
Cautions.	[[0300] The fisk of drug dependence is high.

This document was released under the Feedom of Information Act, 1989.

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	28	0	Novacodone	Sandoz Pty Ltd
		hydrochloride 10 mg (controlled release)			OxyContin	Mundipharma Pty Limited
					Oxycodone Sandoz	Sandoz Pty Ltd
	8386J	Tablet containing oxycodone	28	0	Novacodone	Sandoz Pty Ltd
		hydrochloride 20 mg (controlled release)			OxyContin	Mundipherma Pty Limited
					Oxycodone Sandoz	Sandoz Pty Ltd
	8387K	Tablet containing oxycodone	28	0	Novacodone	Sandoz Pty Ltd
		hydrochloride 40 mg (controlled release)			OxyContin	Mundipharma Pty Limited
					Oxycodone Sandoz	Sandoz Pty Ltd
	8388L	Tablet containing oxycodone	28	0	Novacodone	Sandoz Pty Ltd
		hydrochloride 80 mg (controlled release)		90	OxyContin	Mundipharma Pty Limited
				S	Oxycodone	Sandoz Pty Ltd
			Q,		Sandoz	
Onto many / Days		OFNEDAL Commit	100	· /Ol - /) <u> </u>	

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:	□ Princestricted 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
ris	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 table is 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/organications/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: Pharma cutical 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
.5	Restricted benefit
ris	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
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 a other 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 FBS 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.
2518	[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.
This document was re	[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.
90cm.	[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-
Khis	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:	[Your capital city] [6986] The risk of drug dependence is high.
	[]

PBS indication: Dental Medical Practitioners Nurse practitioners Optometrists Midwives	Category / Program:	GENERAL – General Schedule (Code GE)
PBS indication: Image: Chronic severe pain	Prescriber type:	
Restriction Level / Method: Unrestricted benefit Authority Required – In Writing Authority Required – Telephone/Electronic/Emergency Streamlined Continuing PBS treatment after 1 June 2020. [new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020. [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 (iii) exceeds 12 months and the patients clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse gractitioner 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 been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse gractitioner 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 beyond 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		
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	[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 n.ay be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)
	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857 [Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
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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 Ltg
					Durogesic 12	Janssen-Cilag Pty Ltd
					Fentanyl Sandoz	Sando∠ 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
as relea	[new] Patient must not be opioid naïve AND
40chment was release	[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. Fur her 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/haalth-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 Read-fits Scheme
Cautions:	Pharmaceutical Benefits Scheme Reply Paid 9857 [Your capital city] [6986] The risk of drug dependence is high.
Cautions.	[0300] 1.75 45k of drug dependence is flight.

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
C	⊠Streamlined
Treatment phase:	Initial PBS treatment after 1 June 2020 where patient has been treated with
.6	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 consumation with the patient by another medical practitioner or a palliative care nuise 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.
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	rivist not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
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	Pharmaceutical Benefits Scheme Reply Paid 9857
	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.

	7.9
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
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	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.
	after commendement 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.
(6)	[7901] Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in
100	a formalised arrangement with an agreed management plan. Further
" "	information can be found in the Explanatory Notes for Nurse Practitioners.
his document was rele	[new] Real time online applications for increased maximum quantities/repeats
in the second	may be made using the Online PBS Authorities system (see
C),	www.servicesaustralia.gov.au/organisations/health-
90	professionals/services/medicare/hpos/services/request-authority-using-online- pbs-authorities-hpos)
6	pbs-authorities-ripos)
	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 Lt(i
					Odridoz	.;O\

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 – Telectione/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
inent was release	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
Prescriber instruction:	Inew] 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/hea.th-
	professionals/services/medicare/hpos/services/request-authority-using-online- pbs-authorities-hpos)
	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme
	Reply Paid 9857 [Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
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Category / Program:	GENERAL – General Schedule (Code GE)
	,
Prescriber type:	☐ Dental ☐ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists
	Midwives
PBS indication:	[9729] Chronic severe disabling pain
70.	
Restriction Level / Method:	Unrestricted benefit
	Restricted benefit
	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
C	Streamlined
Treatment phase:	Initial PBS treatment after 1 June 2020 where patient has been treated with
. 6	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 nuise 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
	roust not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
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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/hea/th-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
Tresoriber type:	· · · · · ·
	Midwives
PBS indication:	[9729] Chronic severe disabling pain
120	[0725] Simonio Sovoro disability paint
Restriction Level / Method:	Unrestricted benefit
restriction Ecver/ Michiga.	
	Restricted benefit
	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
Treatment phase:	Continuing PBS treatment after 1 June 2020.
Treatment phase.	Continuing 1 Do troutment after 1 varie 2020.
Clinical criteria:	[new] Patient must have previously received PBS-subsidised treatment with this
O I I O I I	
	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 of 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
Administrative advice:	for up to 1 month treatment and sufficient repeats). [13978] Fentanyl transdermal patches are not recommended in opioid naive
Administrative davise.	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.
	170011 Charad Cara Madely For properlying by pures prostitioners where care of
	[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
100	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
000	www.servicesaustralia.gov.au/organisations/health- professionals/services/medicare/hpos/services/request-authority-using-online-
this document was rele	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 Pty Ltri
					Sandoz	10:

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 paive
sument was rele	[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).

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Category / Program:	ENERAL – General Schedule (Code GE)
Prescriber type:	□Dental ☑Medical Practitioners ☑Nurse practitioners □Optometrists □Midwives
PBS indication: [9	729] Chronic severe disabling pain
	Unrestricted benefit □Restricted benefit □Authority Required – In Writing □Authority Required – Telephone/Electronic/Emergency ☑Streamlined
	uitial PBS treatment after 1 June 2020 where patient has been treated with pioids 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 consumation with the patient by another medical practitioner or a palliative care nuise 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
	rivist not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
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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/hea/th-
	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
Tresonder type:	· · · · · ·
	Midwives
PBS indication:	[9729] Chronic severe disabling pain
1 Bo maication.	[5725] Official Severe disability pain
Destriction Level / Methylic	The contributed have \$64
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.
meannam phase.	Continuing FBS 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.
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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.
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	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
Administrative advice:	for up to 1 month treatment and sufficient repeats). [13978] Fentanyl transdermal parches are not recommended in opioid naive
Auministrative advice.	patients with non-cancer pair vecause 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).
	[nov.] Consider A Making with a moultidissiplinary using coming union to an after
	[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.
.0	[13981] Pharmaceutical benefits that have the form fentanyl 50 microgram/hour patch are equivalent for the purposes of substitution.
this document was rele	[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.
inent	[new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see
90cm	www.servicesaustralia.gov.au/organisations/health- professionals/services/medicare/hpos/services/request-authority-using-online- pbs-authorities-hpos)
(H)	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
					Sandoz	40

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☑ Medical Practitioners ☑ Nurse practifioners ☐ 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
The chinest was rel	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/hea.th-
	professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)
	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme Reply Paid 9857
	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.
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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	□ Dental ☑ Medical Practitioners ☑ Nurse practitioners □ Optometrists ☐ Midwives
PBS indication:	[9729] Chronic severe disabling pain
Restriction Level / Method:	Unrestricted benefit
	Restricted benefit
No.	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
C	⊠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 treament 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 sufficien for up to 1 month treatment and sufficient repeats).
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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	□ Dental ☑ Medical Practitioners ☑ Nurse practitioners □ Optometrists ☐ Midwives
PBS indication:	[9729] Chronic severe disabling pain
Restriction Level / Method:	□Unrestricted benefit □Restricted benefit □Authority Required – In Writing □Authority Required – Telephone/Electronic/Emergency □Streamlined
Treatment phase:	Continuing PBS treatment after 1 June 2020.
Clinical criteria:	[new] Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020.

Prescriber instruction:	[new] Authorities for increased maximum quantities and/or repeats must only be considered for chronic severe disabling pain where the patient has received
	initial authority approval and the total duration of non-PBS and PBS opioid
	analgesic treatment: (i) is less than 12 months; or
	(ii) exceeds 12 months and the palliative care patient is unable to have annual
	pain management review due to their clinical condition; or
	(iii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another
	medical practitioner or a palliative care nurse practitioner in the past 12 months;
	or
	(iv) has exceeded 12 months prior to 1 June 2020 and the patient's pain management and clinical need for continuing opioid treatment has not been
	confirmed through consultation with the patient by another medical practitioner
	or a palliative care nurse practitioner in the past 12 months, but is planned in
	the next 3 months.
	[new] Authority requests extending treatment duration up to 1 month may be
	requested though the Online PBS Authorities system or by calling Services
	Australia.
	Authority requests extending treatment duration beyond 1 month may be
	requested through the Online PBS Authorities system or in writing only and
	must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
Administrative advice:	[13978] Fentanyl transdermal parches are not recommended in opioid naive
	patients with non-cancer pain cecause 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).
	paton (12 miorograms por nour).
	[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.
9	[13983] Pharmaceutical benefits that have the form fentanyl 75 microgram/hour patch are equivalent for the purposes of substitution.
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	[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
103	formalised arrangement with an agreed management plan. Further information
***	can be found in the Explanatory Notes for Nurse Practitioners.
S	[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)
this document was relea	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 praxifioners □ 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
alment was release	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/hea/th
	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:	[Your capital City] [6986] The risk of drug dependence is high.
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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☑ Medical Practitioners ☑ Nurse practitioners ☐ Optometrists ☐ Midwives
PBS indication:	[9729] Chronic severe disabling pain
Restriction Level / Method:	Unrestricted benefit
	Restricted benefit
	☐Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
C	⊠Streamlined
Treatment phase:	Initial PBS treatment after 1 June 2020 where patient has been treated with
.6	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 nuise 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
	for up to 1 month treatment and sufficient repeats).
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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☐ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists
Tresonder type:	· · · · · ·
	Midwives
PBS indication:	[9729] Chronic severe disabling pain
1 Bo maication.	[5725] Official Severe disability pain
Destriction Level / Methylic	The contributed have \$64
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.
meannam phase.	Continuing FBS 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.
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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; or (iii) 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 painted in the next 3 months. [new] Authority requests extending treatment duration are particularly and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month healthent duration and patient patients). Administrative advice: Administrative advice: Administrative advice: Administrative advice: 1(3)78) Fentany transdermal paties are not recommended in opioid naive patients with non-cancer pair ceasures of a high incidence of adverse events in these patients. Patients with sancer pain may be initiated on the lowest strength patch (12 micrograms per hour). [new] Tries treatment is not suitable for 'as-required' pain relief. [13384] Pharmaceutical benefits that have the form fentanyl 100 microgramshour patch are equivalent for the purposes of substitution. [rew] Tries treatment is not suitable for 'as-required' pain relief. [13384] Pharmaceutical benefits that have the form fentanyl 100 microgramshour patch are equivalent for the purposes of substitution. [rew] Tries treatment is not suitable for 'as-required' pain relief. [13384] Pharmaceutical benefits that have th	B 9 1 4 0	T 1A H 19 f 1 1 2 200 11 1 1 1 1 1 1 1 1 1 1 1 1 1
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	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-Cilaç, ^O ty 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 Scho	edule (Code	GE)		
Prescriber type:		☐Dental ☑Medical Prac ☐Midwives	ctitioners [<u>Xi</u>]	Nurse pra	ctitioners	ometrists
PBS indication:		[new] Chronic severe pain	2			

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 PES 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
25	AND
No	[new] Patient must not be opioid naïve
ae nit	AND
Chu	[18096] Patient must have cancer pain OR
This document was t	[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/hpcs/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 explications 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.
40	

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
9.0	Authority Required – In Writing
Nis	☐ 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 repeals must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment: (i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or (ii) exceeds 12 months and the patient's clinical need for continuing opioid treatment has been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months; or (iii) has exceeded 12 months prior to 1 June 2020 and the patient's clinical need for continuing opioid treatment has not been confirmed through consultation with the patient by another medical practitioner or a palliative care nurse practitioner in the past 12 months, but is planned in the next 3 months.
	[new] Authority requests extending treatment duration up to 1 month may be requested though the Online PBS Authorities system or by calling Services Australia.
	Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing only and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

Administrative advice:	[new] Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.
	[new] This treatment is not suitable for 'as-required' pain relief.
	[7901] Shared Care Model: For prescribing by nurse practitioners where care of a patient is shared between a nurse practitioner and medical practitioner in a formalised arrangement with an agreed management plan. Further information can be found in the Explanatory Notes for Nurse Practitioners.
	[new] Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see www.servicesaustralia.gov.au/organisations/health-professionals/services/medicare/hpos/services/request-authority-using-online-pbs-authorities-hpos)
	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme Reply Paid 9857
	[Your capital city]
Cautions:	[6986] The risk of drug dependence is high.

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.

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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.
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	[new] Authority requests extending treatment duration up to 1 month may be
	requested though the Online PBS Authorities system or by calling Services
	Australia.
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	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.
	[now] This treatment is not suitable for 'as required' pain relief
	[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 snared 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.
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2	may be made using the Online PBS Authorities system (see
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	Written authority applications for increased maximum quantities/repeats can
C)),	be uploaded online through HPOS form upload or mailed to:
200	Pharmaceutical Benefits Scheme
0-	Reply Paid 9857
401	[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	Item	Legal Instrument Form	Max.	No.	Brand Name	Responsible Person
Drug	Code	-	Qty	Rpt		•
METHADONE	1606M	Injection containing methadone hydrochloride 10 mg in 1 mL	5	0	Physeptone	Aspen Pharma Pty Ltd
	1609Q	Tablet containing methadone hydrochloride 10 mg	20	0	Physeptone	Aspen Pharma Pty Ltd

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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	□ Dental ☑ Medical Practitioners ☑ Nurse practitioners □ Optometrists ☐ Midwives
PBS indication:	[9729] Chronic severe disabling pain
Restriction Level / Method:	□ Unrestricted benefit □ Restricted benefit □ Authority Required – In Writing □ Authority Required – Telephone/Electronic/Emergency □ Streamlined
Treatment phase:	Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months.
Clinical criteria:	[new] The condition must require daily, continuous, long term treatment AND [new] Patient must not be opioid naïve AND [18096] Patient must have cancer pain OR [new] Patient must have had or would have inadequate pain management with to grated 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: NO	[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/repca's may be made by calling 1800 888 333.
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload of mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857
Cautions:	[6986] The risk of drug dependence is high.
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Category / Program:	GENERAL – General Schedule (Code GE)			
Prescriber type:	□ Dental ☑ Medical Practitioners ☑ Nurse practitioners □ Optometrists ☐ Midwives			
PBS indication:	[9729] Chronic severe disabling pain			
Restriction Level / Method:	Unrestricted benefit			
	Restricted benefit			
	Authority Required – In Writing			
2	Authority Required – Telephone/Electronic/Emergency			
	Streamlined			
Treatment phase:	Initial PBS treatment after 1 June 2020 where patient has been treated with			
5	opioids for more than 12 months.			
Clinical criteria:	[new] The condition must require daily, continuous, long term treatment			
Clinical criteria:	AND			
chu.	[new] Patient must not be opioid naïve			
900	AND			
His	[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.			

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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.
	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.
20	Real time online applications for increased maximum quantities/repeats may be made using the Online PBS Authorities system (see
as telle	www.servicesaustralia.gov.au/organisations/health- professionals/services/medicare/hpos/services/request-authority-using-online- pbs-authorities-hpos)
SUL NO	Phone applications for increased maximum quantities/repeats may be made by calling 1800 888 333.
90chWely Mazker	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to: Pharmaceutical Benefits Scheme Reply Paid 9857
Cautions:	[6986] The risk of drug dependence is high.
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Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☑ Medical Practitioners ☑ Nurse practitioners ☐ Optometrists ☐ Midwives
PBS indication:	[9729] Chronic severe disabling pain

Restriction Level / Method:	Unrestricted benefit
Troomon 20101 / Information	Restricted benefit
	Authority Required – In Writing
	Authority Required – Telephone/Electronic/Emergency
Treatment phase:	Streamlined 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.
	401,
	[new] Authority requests extending treatment duration up to 1 month may be
	requested though the Online PBS Authorities system or by calling Services Australia.
	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
Administrative advice:	for up to 1 month treatment and sufficient repeats). [new] Consider consultation with a multidisciplinary pain service prior to, or after
Administrative advice.	commencement of this medication.
0	
e c	[new] This treatment is not recommended for use in ambulant patients.
This document was release	[new] This treatment is not suitable for 'as-required' pain relief.
40	[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
0	formalised arrangement with an agreed management plan. Further information
	can be found in the Explanatory Notes for Nurse Practitioners.
C	[new] Real time online applications for increased maximum quantities/repeats
80	may be made using the Online PBS Authorities system (see
is s	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 quantitics/repeats can be
	Written authority applications for increased maximum quantities/repeats can be uploaded online through HPOS form upload or mailed to:
	Pharmaceutical Benefits Scheme
	Reply Paid 9857
Cautions:	[6986] The risk of drug dependence is high.
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