

5.25 METHADONE, Tablet 5 mg, Methadone-AFT, AFT Pharmaceuticals (AU) Pty Ltd

1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule Authority Required (STREAMLINED) listing and Palliative Care Authority Required (Telephone/Online) listing of methadone 5 mg tablet (Methadone-AFT 5 mg) under the same circumstances as the currently listed methadone 10 mg tablet.

2 Background

- 2.1 Methadone is currently listed on the PBS under General Schedule Authority Required (STREAMLINED) and Palliative Care Authority Required (Telephone/Online).
- 2.2 Methadone is listed on the PBS for the following indications:
- Chronic severe disabling pain
 - Severe disabling pain
 - Opioid dependence
- 2.3 Methadone is currently listed on the PBS in the following forms:
- Methadone hydrochloride 10 mg tablet
 - Methadone hydrochloride 10 mg/mL injection
 - Methadone hydrochloride 5 mg/mL oral liquid, 1 L
 - Methadone hydrochloride 5 mg/mL oral liquid, 200 mL

Registration status

- 2.4 Methadone-AFT 5 mg was Therapeutic Goods Administration (TGA) registered on 27 February 2023.
- 2.5 Methadone-AFT 5 mg was approved for the same indications as methadone 10 mg tablet.
- 2.6 The TGA approval letter stated that generic methadone hydrochloride 5 mg and 10 mg tablets (Methadone AFT) included data that established to the TGA's satisfaction that the products can be considered bioequivalent to Physeptone 10 mg tablet (hereafter referred to as Physeptone). The TGA noted that the data supplied demonstrated that 2 x 5 mg Methadone AFT tablets would be equivalent to 1 x 10 mg Physeptone tablet.

Previous PBAC consideration

- 2.7 Methadone 5 mg tablets have not been previously considered by the PBAC for management of chronic severe disabling pain.
- 2.8 The PBAC considered a gap analysis of opioids listed on the PBS at its September 2024 meeting. The submission noted the PBAC advised that it is important to maintain a range of opioid medicines (and dose forms) on the PBS to ensure prescribers have access to suitable therapeutic options for pain management that can be tailored to a patient’s individual circumstances (Gap analysis of opioids listed on the PBS, web outcome, September 2024 PBAC meeting).

3 Requested listing

- 3.1 The submission requested listing Methadone AFT 5 mg for the treatment of chronic severe disabling pain where alternative pain management therapies have failed. As the submission did not present proposed restrictions, the Secretariat proposed the following new listing, under the same circumstances as the currently listed methadone 10 mg tablet (1609Q, 12520Y).

Add new medicinal product as follows:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METHADONE						
methadone hydrochloride 5 mg tablet, 20		NEW	1	20	0	METHADONE-AFT
Restriction Summary: 15995 / Treatment of Concept: 15996						
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)					
8211	Caution: The risk of drug dependence is high.					
Prescribing rule level	Administrative Advice: This treatment is not suitable for 'as-required' pain relief					
	Administrative Advice: This treatment is not recommended for use in ambulant patients					
	Administrative Advice: Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication					
	Administrative Advice: 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]					
Indication: Chronic severe disabling pain						

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	Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months
	Clinical criteria:
	The condition must require daily continuous, long term opioid treatment
	AND
	Clinical criteria:
	Patient must not be opioid naïve
	AND
	Clinical Criteria:
	Patient must have cancer pain; or
	Patient must have had or would have inadequate pain management with maximum tolerated doses of non- opioid and other opioid analgesics; or
	Patient must be unable to use non-opioid analgesics due to contraindications or intolerance
	Treatment criteria:
	Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner
	Prescribing Instructions: Authorities for increased maximum quantities and/or repeats under this restriction must only be considered for chronic severe disabling pain where the total duration of non-PBS and PBS opioid analgesic treatment is less than 12 months.
	Prescribing Instructions: Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
Restriction Summary: 15999 / Treatment of Concept: 15994	
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)
Prescribing rule level	Caution: The risk of drug dependence is high.
	Administrative Advice: This treatment is not suitable for 'as-required' pain relief.
	Administrative Advice: This treatment is not recommended for use in ambulant patients.
	Administrative Advice: Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.
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	Indication: Chronic severe disabling pain
	Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months

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	Clinical criteria:
	The condition must require daily, continuous, long term opioid treatment
	AND
	Clinical criteria:
	Patient must not be opioid naïve
	AND
	Clinical criteria:
	Patient must have cancer pain; or
	Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or
	Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance
	Treatment criteria:
	Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner
	Prescribing Instructions: 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.
	Prescribing Instructions: Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
	Prescribing Instructions: Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).
Restriction Summary: 15998 / Treatment of Concept: 16000	
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)
Prescribing rule level	Caution: The risk of drug dependence is high.
	Administrative Advice: This treatment is not suitable for 'as-required' pain relief.
	Administrative Advice: This treatment is not recommended for use in ambulant patients.
	Administrative Advice: Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication.

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	<p>Administrative Advice: 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]</p>
	<p>Indication: Chronic severe disabling pain</p>
	<p>Treatment Phase: Continuing PBS treatment after 1 June 2020</p>
	<p>Clinical criteria:</p>
	<p>Patient must have previously received PBS-subsidised treatment with this form of this drug for this condition after 1 June 2020</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner</p>
	<p>Prescribing Instructions: 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.</p>
	<p>Prescribing Instructions: Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.</p>
	<p>Prescribing Instructions: Authority requests extending treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).</p>

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
METHADONE					
methadone hydrochloride 5mg tablet, 20	NEW	6	120	0	METHADONE-AFT
Restriction Summary: 11696 / Treatment of Concept:11696					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL – General Schedule Palliative Care (Code PL)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required				

Prescribing rule level	Caution: The risk of drug dependence is high
	Administrative Advice: This treatment is not suitable for 'as-required' pain relief.
	Administrative Advice: This treatment is not recommended for use in ambulant patients.
	Administrative Advice: 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). 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]
	Indication: Severe disabling pain
	Clinical criteria:
	Patient must not be opioid naive
	AND
	Clinical Criteria:
	Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or
	Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance
	Treatment criteria:
	Patient must be undergoing palliative care
	Prescribing Instructions: Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).

4 Comparator

- 4.1 The submission nominated methadone 10 mg tablet (Physeptone) as the main comparator. This was appropriate.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from individuals (3) via the Consumer Comments facility on the PBS website. The comments described the effects of chronic pain as debilitating and the impacts on quality of life included limited ability to work and interact with family and friends. The comments supported the availability of methadone 5 mg for chronic severe disabling pain.

Clinical claim

- 5.3 The submission did not explicitly state a clinical claim for Methadone-AFT 5 mg.

- 5.4 The PBAC considered that a claim of non-inferior efficacy and non-inferior safety compared to methadone 10 mg tablets is reasonable where two 5 mg tablets are used in place of one 10 mg tablet. The PBAC noted this aligns with the TGA’s bioequivalence statement.

Economic analysis

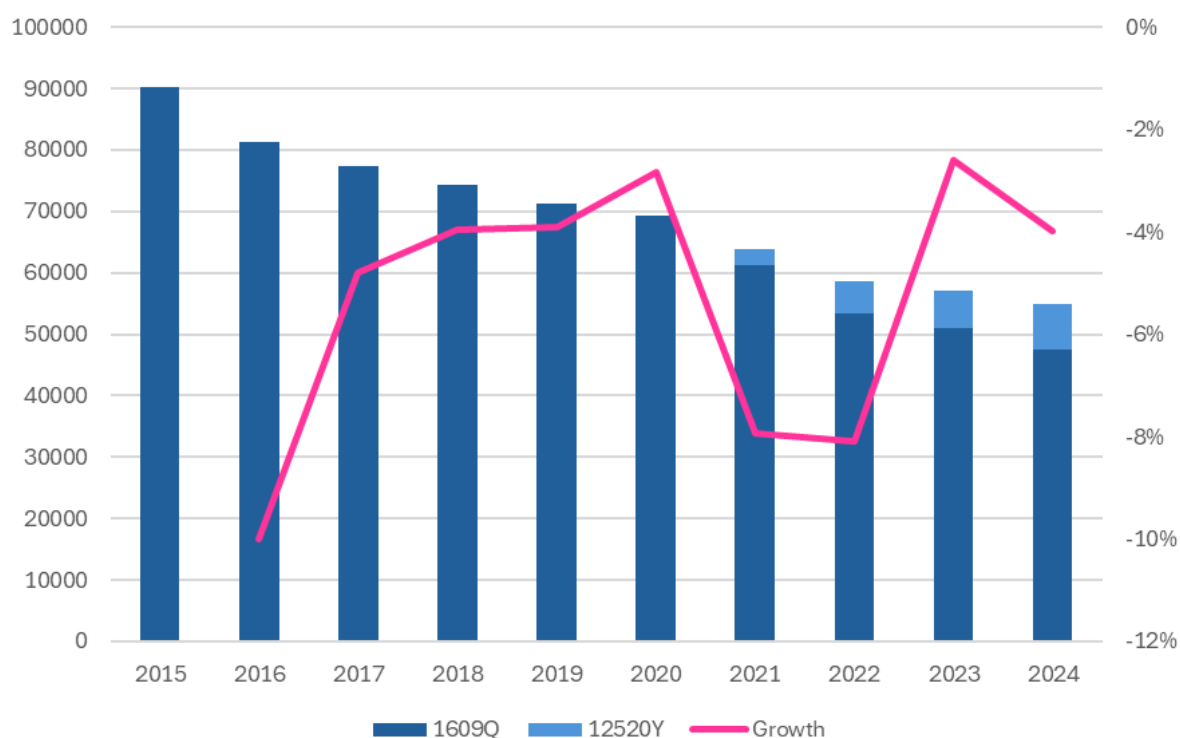
- 5.5 The submission proposed methadone 5 mg tablets be cost-minimised to methadone 10 mg tablets.
- 5.6 The submission requested an approved ex-manufacturer price (AEMP) of \$3.70 for a quantity of 20 tablets. The proposed price was not consistent with a cost-minimisation approach to methadone 10 mg tablets. No justification was provided by the sponsor.

Estimated PBS usage and financial implications

- 5.7 The submission presented the estimated extent of use, cost of Methadone-AFT 5 mg to the PBS/RPBS and the net financial implications to the PBS/RPBS.
- 5.8 The submission proposed listings on both General Schedule and Palliative Care Program. Each program has different maximum quantities and therefore different Dispensed Price for Maximum Quantity (DPMQ). Consequently the UCM should have separated the general and palliative care programs.
- 5.9 The submission’s assumption for market growth rates were based on PBS Item Reports of methadone 10 mg script for PBS/RPBS over the last 10 years. The submission noted there has been a decrease in the total number of prescriptions of methadone 10 mg supplied each year (Figure 1). The submission also noted there has been an increase in the number of opioid scripts for palliative care patients from the second quarter of 2021 which was likely due to a change in the palliative care schedule on 1 June 2020. The submission stated it is estimated a small incremental increase on methadone scripts are expected in palliative care schedule in the coming years.

Figure 1. Number of methadone 10 mg prescriptions and rate of growth from 2015-2024

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Source: Figure 1 of submission (p7)

5.10 The submission’s estimate for number of scripts was based on a 4% decline in methadone 10 mg tablets and 10% growth in Methadone-AFT 5 mg over the forward 6 years. It was unclear how the fixed growth rates were derived. The projected growth rates should be determined by applying an appropriate trend line and extrapolating based on the historical data.

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed ^a	■ ¹	■ ²	■ ²	■ ²	■ ³	■ ³
Estimated financial implications of Methadone-AFT 5mg						
Cost to PBS/RPBS less co-payment	■ ⁴	■ ⁴	■ ⁴	■ ⁴	■ ⁴	■ ⁴
Estimated financial implications of methadone 10 mg tablet						
Cost to PBS/RPBS less co-payment	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵
Net financial implications						
Net cost to PBS/RPBS	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵	■ ⁵

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Utilisation and Cost Model Workbook (Further updates to the UCM was provided by the Department)

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

² 5,000 to < 10,000¹

³ 10,000 to < 20,000

⁴ \$0 to < \$10 million

⁵ net cost saving

5.11 The submission estimated that 44,550 scripts for Methadone-AFT 5 mg would be supplied over the first six years of listing (assuming uptake is 5% in Year 1, increasing to 25% in Year 6).

5.12 The submission estimated a net save to the PBS/RPBS of \$0 to < \$10 million in Year 6 of listing Methadone-AFT, with a total net save to the PBS of \$0 to < \$10 million over the first 6 years of listing.

Quality use of medicines

5.13 The submission claimed that Methadone-AFT offers additional benefits and may serve to further improve health and economic outcomes an alternative option rather than a replacement for higher dose formulations by:

- Allowing for more precise dose titration.
- Minimising the risk of adverse events.
- Improving patient adherence by reducing the need of tablet splitting

6 PBAC Outcome

6.1 The PBAC recommended the listing of methadone 5 mg tablet as a General Schedule (STREAMLINED) and Palliative Care (Telephone/Online) listing under the same

circumstances as the currently listed methadone 10 mg tablet for the management of chronic severe disabling pain and severe disabling pain.

- 6.2 The PBAC noted that the TGA established 2 x 5 mg methadone tablet is bioequivalent to 1 x methadone 10 mg tablet.
- 6.3 The PBAC considered methadone 10 mg tablet as the appropriate comparator.
- 6.4 The PBAC noted the submission did not provide any justification for the proposed price. The PBAC considered that an equivalent cost per mg to methadone 10 mg tablets would be an appropriate approach or that the Department may take into account guidelines for the pricing of half strength formulations in this instance.
- 6.5 The PBAC noted the UCM would need to be revised as detailed in paragraph 5.8 and 5.10.
- 6.6 The PBAC advised that, because methadone 5 mg tablet is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the other listed strengths of methadone, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new item:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
METHADONE					
methadone hydrochloride 5 mg tablet, 20	NEW	1	20	0	METHADONE-AFT
Restriction Summary: 15995 / Treatment of Concept:15996					
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Caution: The risk of drug dependence is high.					
Prescribing rule level	Administrative Advice: This treatment is not suitable for 'as-required' pain relief				
	Administrative Advice: This treatment is not recommended for use in ambulant patients				
	Administrative Advice: Consider consultation with a multidisciplinary pain service prior to, or after commencement of this medication				

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	<p>Indication: Chronic severe disabling pain</p>
	<p>Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for less than 12 months</p>
	<p>Clinical criteria:</p>
	<p>The condition must require daily continuous, long term opioid treatment</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not be opioid naïve</p>
	<p>AND</p>
	<p>Clinical Criteria:</p>
	<p>Patient must have cancer pain; or</p>
	<p>Patient must have had or would have inadequate pain management with maximum tolerated doses of non- opioid and other opioid analgesics; or</p>
	<p>Patient must be unable to use non-opioid analgesics due to contraindications or intolerance</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner</p>
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<p>Restriction Summary: 15999 / Treatment of Concept: 15994</p>	
<p>Concept ID (for internal Dept. use)</p>	<p>Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)</p>
	<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners</p>
	<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)</p>
<p>Prescribing rule level</p>	<p>Caution: The risk of drug dependence is high.</p>
	<p>Administrative Advice: This treatment is not suitable for 'as-required' pain relief.</p>
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	Indication: Chronic severe disabling pain
	Treatment Phase: Initial PBS treatment after 1 June 2020 where patient has been treated with opioids for more than 12 months
	Clinical criteria:
	The condition must require daily, continuous, long term opioid treatment
	AND
	Clinical criteria:
	Patient must not be opioid naïve
	AND
	Clinical criteria:
	Patient must have cancer pain; or
	Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or
	Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance
	Treatment criteria:
	Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner
	<p>Prescribing Instructions: 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:</p> <p>(i) exceeds 12 months and the palliative care patient is unable to have annual pain management review due to their clinical condition; or</p> <p>(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</p> <p>(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.</p>
	Prescribing Instructions: Palliative care nurses may conduct annual review under this item for the treatment of palliative care patients only.
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Restriction Summary: 15998 / Treatment of Concept: 16000	
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL - General Schedule (Code GE)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners

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	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)
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	Administrative Advice: This treatment is not suitable for 'as-required' pain relief.
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	Indication: Chronic severe disabling pain
	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
	Treatment criteria:
	Must be treated by a health practitioner who is any of: (i) a medical practitioner, (ii) an authorised PBS prescriber who is not a medical practitioner, but who is: (a) sharing care of the patient with at least one medical practitioner; (b) intending to share care of the patient with a medical practitioner
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METHADONE						
methadone hydrochloride 5mg tablet, 20		NEW	6	120	0	METHADONE-AFT
Restriction Summary: 11696 / Treatment of Concept:11696						
Concept ID (for internal Dept. use)	Category / Program: <input checked="" type="checkbox"/> GENERAL – General Schedule Palliative Care (Code PL)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners					
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Prescribing rule level	Caution: The risk of drug dependence is high					
	Administrative Advice: This treatment is not suitable for 'as-required' pain relief.					
	Administrative Advice: This treatment is not recommended for use in ambulant patients.					
	Administrative Advice: 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). 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]					
Indication: Severe disabling pain						
Clinical criteria:						
Patient must not be opioid naive						
AND						
Clinical Criteria:						
Patient must have had or would have inadequate pain management with maximum tolerated doses of non-opioid and other opioid analgesics; or						
Patient must be unable to use non-opioid and other opioid analgesics due to contraindications or intolerance						
Treatment criteria:						
Patient must be undergoing palliative care						
Prescribing Instructions: Authority requests for treatment duration up to 1 month may be requested through the Online PBS Authorities system or by calling Services Australia. Authority requests extending treatment duration beyond 1 month may be requested through the Online PBS Authorities system or in writing and must not provide a treatment duration exceeding 3 months (quantity sufficient for up to 1 month treatment and sufficient repeats).						

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers

applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

9 Sponsor's Comment

The sponsor had no comment.