

5.22 OXYCODONE

Capsule containing oxycodone hydrochloride 5 mg, OxyNorm[®], Mundipharma Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested a Restricted Benefit listing for a new pack size/maximum quantity (10 capsules) of oxycodone 5 mg capsules for patients with severe disabling pain who are unresponsive to non-opioid analgesics.
- 1.2 Oxycodone 5 mg capsules and tablets are currently available on the PBS in a maximum quantity of 20 capsules or tablets. The submission claimed that the new pack size/maximum quantity aimed to improve Quality Use of Medicines.

2 Requested listing

- 2.1 The submission proposes no changes to the existing listing with the exception of making an additional maximum quantity of 10 available.
- 2.2 Suggestions and additions proposed by the Secretariat to the requested listing are added in italics and suggested deletions are crossed out with strikethrough.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
OXYCODONE Oxycodone hydrochloride 5 mg capsule, 10	1	0	\$	OxyNorm [®] Mundipharma Pty Ltd

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioner <input checked="" type="checkbox"/> Nurse Practitioner
Severity:	Severe
Condition:	Disabling pain
PBS Indication:	Severe disabling pain
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must be unresponsive to non-opioid analgesics.

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Prescriber Instructions:	Authorities for increased maximum quantities and/or repeats will be granted only for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
Administrative Advice:	Authorities for increased maximum quantities and/or repeats will be granted only for: (i) severe disabling pain associated with proven malignant neoplasia; or (ii) chronic severe disabling pain not responding to non-opioid analgesics where the total duration of opioid analgesic treatment is less than 12 months; or (iii) first application for treatment beyond 12 months of chronic severe disabling pain not responding to non-opioid analgesics where the patient's pain management has been reviewed through consultation by the patient with another medical practitioner, and the clinical need for continuing opioid analgesic treatment has been confirmed. The date of the consultation must be no more than 3 months prior to the application for a PBS authority. The full name of the medical practitioner consulted and the date of consultation are to be provided at the time of application; or (iv) subsequent application for treatment of chronic severe disabling pain not responding to non-opioid analgesics where a PBS authority prescription for treatment beyond 12 months has previously been issued for this patient.
Cautions:	The risk of drug dependence is high.

Category / Program:	GENERAL - General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Dental
Severity:	Severe
Condition:	Disabling pain
PBS Indication:	Severe disabling pain
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must be unresponsive to non-opioid analgesics.
Prescriber Instructions:	Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.
Administrative Advice:	
Cautions:	The risk of drug dependence is high.

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

3 Background

- 3.1 Oxycodone (OxyNorm®) was TGA registered for the management of opioid responsive, moderate to severe pain. The 10-capsule pack was TGA registered on 22 October 2018, which also consisted of a label change related to 'Short Course Pack' as well as a change of colour to differentiate from the 20-capsule pack.
- 3.2 The submission claimed the new 10-capsule pack was introduced in response to the recent TGA review 'Prescription strong (Schedule 8) opioid use and misuse in Australia'¹ which considered the appropriateness of pack sizes for strong opioids intended for short-term use.
- 3.3 At the time of this submission, the TGA review was ongoing and no regulatory response to reduce pack-sizes had been introduced; however, the Society of Hospital Pharmacists of Australia had recommended smaller pack sizes of oxycodone².

4 Comparator

- 4.1 The minor submission nominated oxycodone 5 mg (20 capsules, PBS item number 8464L and 5191F) as the main comparator.
- 4.2 The Sponsor requested a higher price than the comparator on a per-tablet basis.
- 4.3 The PBAC noted that this submission seeks to list a new maximum quantity/pack size of an already listed Pharmaceutical Item; thus there is no need to identify a comparator.

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

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item as it was a minor submission.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

- 5.3 The minor submission presented no clinical trials.
- 5.4 The submission referenced a systematic review into the frequency at which clinician-prescribed opioids were unused in post-operative patients and reasons for this, and

¹ TGA Jan 2018, 'Prescription strong (Schedule 8) opioid use and misuse in Australia' p11

² Attachment to submission 'SHPA Letter – Peter Fowler'.

storage and disposal practices by these patients³. The review found that across 810 patients and 6 clinical trials in the United States, 67% to 92% of patients reported unused opioids post-surgery. Among opioids obtained by surgical patients, 42% to 71% of all tablets went unused. In two studies examining storage safety, 73% to 77% of patients reported that their prescription opioids were not stored in locked containers. The review concluded that best practices to reduce the over-supply of opioids after surgery are needed, especially given clinician-prescribed opioid analgesics are commonly diverted for non-medical use.

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

Economic analysis

- 5.5 The minor submission presented no economic comparison.
- 5.6 The Sponsor requested an approved ex-manufacturer price (AEMP) of \$ [REDACTED] per 10 capsules of 5 mg oxycodone with a DPMQ of \$ [REDACTED]. The proposed AEMP is identical to the currently listed 20 capsule pack, representing a [REDACTED]% price increase per capsule of oxycodone for the new pack. The Sponsor claimed that the purchase price of both of the packs for the company is [REDACTED].
- 5.7 The Pre-PBAC response stated that the proposed price [REDACTED], since some patients are currently prescribed 20 capsules when only 10 capsules are required. It also claimed the reduced toxicity effects of a smaller pack size/maximum quantity warrants a higher price.
- 5.8 Section 84AK of the *National Health Act 1953* (the Act) defines the *pricing quantity* of a listed brand of a pharmaceutical item as the "lowest of any pack quantity of any listed brand of the pharmaceutical item". Section 85D of the Act requires different pack sizes of the same pharmaceutical item are to be priced proportionally.

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

Estimated PBS usage & financial implications

- 5.9 The Sponsor claimed that the proposed listing of the 10-capsule pack would be cost-neutral to PBS, as it would only displace the larger packs size, and the market was not expected to grow.
- 5.10 The Sponsor also claimed that the current 20-capsule pack of OxyNorm is sold at a gross loss of [REDACTED]% per pack, and that the cost-of-goods for the 10-capsule pack is [REDACTED] the 20-capsule pack. The submission provided no data to support this claim.

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

³ Bicket MC, L. J. (2017, November 1). Prescription Opioid Analgesics Commonly Unused After Surgery: A Systematic Review. *JAMA Surg.* 2017 November 01; 152(11): 1066–1071. doi:10.1001/jamasurg.2017.0831.

6 PBAC Outcome

- 6.1 The PBAC recommended the Restricted Benefit listing of a new maximum quantity (MQ) of 10 for oxycodone 5 mg capsules and tablets for short-term use for patients with severe disabling pain unresponsive to non-opioid analgesics. The PBAC noted the requirements of the Act for proportional pricing and requested the Department negotiate a new price for the 10 pack consistent with these requirements.
- 6.2 The PBAC noted that the current PBS listing of 20 capsules of 5 mg oxycodone has the flexibility to allow prescriber to prescribe a broken pack to patients. The PBAC noted that the sponsor did not account for the prescribing of a lower quantity as a broken pack in its submission.
- 6.3 The PBAC recommended the new listing for an MQ of 10 be differentiated from the current restriction for an MQ of 20 by indicating the MQ of 10 is intended for short term (2 – 3 days) pain relief of acute severe pain that is non-responsive to non-opioid analgesics, and by not allowing any increase in the maximum quantity or number of repeats.
- 6.4 The PBAC acknowledged the recent TGA review, 'Prescription strong (Schedule 8) opioid use and misuse in Australia', which proposed an option for the Sponsors to register, and make available for supply, smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain. It also noted the recommendation for smaller pack-sizes of oxycodone was supported by the Society of Hospital Pharmacists of Australia. The PBAC acknowledged the potential quality use of medicine benefit of reduced maximum quantities for opioids used in the acute pain setting (e.g. after surgery).
- 6.5 The PBAC noted that its recommendation was for a new maximum quantity of an already listed Pharmaceutical Item and advised that because the recommended change to the listing was not expected to alter the efficacy or toxicity of the treatment, or address a high and urgent unmet clinical need, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.6 The PBAC noted oxycodone is currently available for prescribing by nurse practitioners for patients with severe disabling pain who are unresponsive to non-opioid analgesics.
- 6.7 The Safety Net Early Supply Rule does not currently apply to oxycodone.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
OXYCODONE Oxycodone hydrochloride 5 mg 1 0 capsule/tablet, 10			Various Various

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Medical Practitioner <input checked="" type="checkbox"/> Nurse Practitioner
Episodicity	Acute
Severity:	Severe
Condition:	Disabling pain
PBS Indication:	Acute severe disabling pain.
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
Clinical criteria:	The treatment must be for short term term (2- 3 days) acute severe disabling pain, AND The condition must be unresponsive to non-opioid analgesics.
Prescriber Instructions:	
Administrative Advice:	Note: No increase in the maximum quantity or number of units may be authorised. No increase in the number of repeats may be authorised.
Cautions:	The risk of drug dependence is high.

Category / Program:	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Dental
Severity:	Severe
Condition:	Disabling pain
PBS Indication:	Severe disabling pain
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required – In Writing <input type="checkbox"/> Authority Required – Telephone/Electronic/Emergency <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must be unresponsive to non-opioid analgesics.

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Prescriber Instructions:	<i>Prescribing of drugs of addiction by dentists is not permitted in some States/Territories.</i>
Administrative Advice:	
Cautions:	<i>The risk of drug dependence is high.</i>

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor looks forward to working with the Department to give effect to the PBAC's recommendations.