

5.24 OXYCODONE WITH NALOXONE

Tablet (controlled release) containing oxycodone hydrochloride 60 mg with naloxone hydrochloride 30 mg, 28 tablets, Tablet (controlled release) containing oxycodone hydrochloride 80 mg with naloxone hydrochloride 40 mg, 28 tablets
Targin[®],
Mundipharma Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested an Authority Required listing for two additional strengths of oxycodone with naloxone for the treatment of moderate to severe pain unresponsive to non-opioid analgesia under the same conditions as the currently listed strengths.

2 Requested listing

- 2.1 The submission requested listing the additional strengths of oxycodone with naloxone with the same General Schedule listing as the existing strengths: 2.5 mg/1.25 mg, 15 mg/7.5 mg, 30 mg/15 mg, 20 mg/10 mg and 40 mg/20 mg.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
Oxycodone hydrochloride 60 mg + naloxone hydrochloride 30 mg: modified release, tablet, 28	1	0	\$ [REDACTED]	Targin®	Mundipharma Pty Ltd
Oxycodone hydrochloride 80 mg + naloxone hydrochloride 40 mg: modified release, tablet, 28	1	0	\$ [REDACTED]		

Category / Program	GENERAL – General Schedule (Code-GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Chronic severe disabling pain
PBS Indication:	Chronic 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 <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined

Clinical criteria:	The condition must be unresponsive to non-opioid analgesics.
Administrative Advice	<p><u>Note</u> Authorities for increased maximum quantities and/or repeats will be granted only for:</p> <p>(i) chronic severe disabling pain associated with proven malignant neoplasia; or</p> <p>(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</p> <p>(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</p> <p>(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.</p> <p><u>Note</u> 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.</p>
Cautions	The risk of drug dependence is high.

3 Background

- 3.1 The PBAC recommended that the Department consult with organisations representing physicians experienced in pain management.
- 3.2 Oxycodone with naloxone was TGA approved in March 2010 for the management of moderate to severe chronic pain unresponsive to non-narcotic analgesia.
- 3.3 Oxycodone with naloxone was initially recommended for PBS listing at the November 2010 PBAC meeting in a limited range of strengths. At the March 2015 PBAC meeting, the PBAC deferred making a recommendation regarding the proposed general schedule listing of additional strengths of oxycodone with naloxone pending consultation with organisations representing physicians experienced in pain management. At the November 2015 meeting, the PBAC recommended listing the strengths 2.5 mg/1.25 mg, 15 mg/7.5 mg and 30 mg/15 mg.
- 3.4 At the November 2015 meeting, in accordance with subsection 101(3BA) of the *National Health Act 1953*, the PBAC advised that oxycodone with naloxone should not be treated as interchangeable on an individual patient basis with any other drug.

- 3.5 The requested strengths have not previously been considered by the PBAC.

For more detail on PBAC's view, see section 7 "PBAC outcome"

4 Clinical place for the proposed therapy

- 4.1 The submission stated that the two additional strengths were to enable medical practitioners to titrate in greater increments than what was currently available with treatment with oxycodone alone, which would avoid the unnecessary side effects in order to achieve effective chronic pain control.
- 4.2 The submission stated that the higher strengths provided clinicians and patients with the choice of an opioid that can meet their pain requirements whilst improving outcomes of opioid induced constipation (OIC).
- 4.3 The submission stated that in current clinical practice, a maximum daily dose of oxycodone with naloxone 160 mg/80 mg can only be achieved by combining more than one of the already listed tablet strengths. The sponsor expects that the addition dose strengths will allow for a simplified pain management therapy for patients requiring higher doses of controlled release oxycodone.

For more detail on PBAC's view, see section 7 "PBAC outcome"

5 Comparator

- 5.1 The minor submission did not nominate a comparator.

6 Consideration of the evidence

Sponsor hearing

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

Consumer comments

- 6.2 The PBAC noted and welcomed the input of health care professionals (1) via the Consumer Comments facility on the PBS website. The comment described the benefit of treatment with oxycodone hydrochloride with naloxone hydrochloride, highlighting the availability of higher strengths which would allow for the administration of fewer tablets to improve patient compliance. The PBAC noted that this advice was supportive of the claims made by the submission.

Economic analysis

- 6.3 The price proposed for the two additional strengths was calculated using the Pricing Manual pricing derivation approach, based on a 20% premium over the comparable oxycodone presentation.

Estimated PBS usage & financial implications

- 6.4 The submission used a market share approach to estimate the financial impact of the proposed listing. The submission proposed there will be no net change in the number of prescriptions for oxycodone and consequently no real change in the cost to the PBS/RPBS.

7 PBAC Outcome

- 7.1 The PBAC recommended the listing of the new strengths of oxycodone with naloxone for the treatment of chronic severe disabling pain.
- 7.2 The PBAC noted the market for both oxycodone and oxycodone with naloxone is growing but did not consider that the addition of extra strengths to the PBS would add to that growth.
- 7.3 The PBAC noted that the TGA had increased the maximum allowable dose per day for oxycodone. The PBAC also noted that currently there was no corresponding 60 mg oxycodone monotherapy dose available on the PBS. The PBAC noted that the two additional strengths may assist in reducing the number of tablets required for the treatment of chronic severe disabling pain in some patients.
- 7.4 The PBAC noted that in a palliative care setting the administration of higher doses would be required and may be assisted by the requested listing.
- 7.5 The PBAC advised under Section 101(3BA) of the *National Health Act, 1953* that oxycodone with naloxone should not be treated as interchangeable on an individual basis with any other drug.
- 7.6 The PBAC advised that oxycodone with naloxone was suitable for prescribing by nurse practitioners under a shared care model.
- 7.7 The PBAC recommended that the Early Supply Rule should not apply, as it currently does not apply to the existing strengths.
- 7.8 The PBAC noted that this submission is not eligible for an Independent Review because the PBAC has made a positive recommendation.

Outcome:

Recommended

Addendum:

Subsequent to the November 2016 PBAC meeting the PBAC considered at December Special PBAC meeting whether the new strengths of oxycodone with naloxone met the criteria for a ruling under section 101 (4AC) of the *National Health Act 1953* for the requested strengths.

The PBAC provided the following advice:

The PBAC reaffirmed its advice under section 101 (4AC) of the *National Health Act 1953* that the additional strengths of oxycodone with naloxone meet the criteria under this section.

8 Recommended listing

8.1 Add new item

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Clinical criteria:	The condition must be unresponsive to non-opioid analgesics.

<p>Administrative Advice</p>	<p><u>Note</u> Authorities for increased maximum quantities and/or repeats will be granted only for: (i) chronic 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. <u>Note</u> 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.</p>
<p>Cautions</p>	<p>The risk of drug dependence is high.</p>

9 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.

10 Sponsor's Comment

The Sponsor welcomes the PBACs decision and will be working towards ensuring that patients have access to a broader choice of medications for chronic severe disabling pain.