

5.33 OXYCODONE HYDROCHLORIDE modified release tablet, 5 mg; Oxycodone Sandoz® Sandoz Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the PBS listing of a 5 mg strength of modified release oxycodone.

2 Requested listing

- 2.1 The submission requested listing the 5 mg strength with the same General Schedule listing as the existing strengths: 10 mg, 20 mg, 40 mg and 80 mg.
- 2.2 Expert clinicians have advised that “narcotic” is an outdated term that has been replaced with “opioid” in clinical practice.

3 Background

- 3.1 The 5 mg strength oxycodone was previously listed on the PBS under the brand name OxyContin and was de-listed in April 2014 following a deletion request from that sponsor; the product was discontinued as it had been established there was no pressing clinical need to retain that strength.
- 3.2 In November 2014 the PBAC noted that use of opioids, particularly oxycodone and paracetamol + codeine, is increasing. The PBAC advised the Minister that a systematic approach should be undertaken to review and target the use of these opioids to promote the Quality Use of Medicines.
- 3.3 The PBAC has previously considered the issues of opioid subsidy at various times, including at a stakeholder meeting in 2011 and at the August special PBAC meeting in 2012.

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 re-introduction of the 5 mg strength would allow prescribers more flexibility when prescribing pain medications. The submission contended that following deletion of the 5 mg strength, prescribers have been forced to either prescribe the 5 mg oxycodone + 2.5 mg naloxone therapy, or move patients to the higher strength (10 mg) PBS listed oxycodone, and submitted that this compromised Quality Use of Medicines (QUM).

For more detail on PBAC’s view, see section 7 “PBAC outcome”

5 Comparator

- 5.1 The 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 that no consumer comments were received for this item.

Economic analysis

- 6.3 The submission proposed that the 5 mg strength be priced approximately ■% less than the current AEMP for Targin (oxycodone + naloxone) 5mg/2.5mg.

Estimated PBS usage & financial implications

- 6.4 It appears that the submission assumed that following re-listing of the 5 mg strength, prescribers would move patients from oxycodone 5 mg + naloxone 2.5 mg to oxycodone 5 mg, however financial estimates were not presented.

7 PBAC outcome

- 7.1 The PBAC rejected the proposed General schedule listing of the oxycodone 5 mg strength.
- 7.2 The PBAC noted that another sponsor's 5mg presentation of oxycodone had been removed from the PBS at the request of that sponsor. The PBAC recalled that as a standard part of a request to delist a product from the PBS, it must be established that there is no pressing clinical need for the product in question. Having been satisfied that this was the case for oxycodone 5mg, the PBAC considered that this submission had not established a convincing argument that a clinical need for this strength now existed.
- 7.3 The PBAC noted that the submission did not provide financial estimates.
- 7.4 The PBAC noted expert clinician advice that "narcotic" is an outdated term that has been replaced with "opioid" in clinical practice, and accepted that the clinical criteria "The condition must be unresponsive to non-narcotic analgesics" for currently listed opioids be changed to "The condition must be unresponsive to non-opioid analgesics". The PBAC noted that this change would impact a significant number of listings and the timing of implementing the change would need to be prioritised.
- 7.5 The PBAC noted that this submission is not eligible for an Independent Review.

Outcome:

Rejected

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 had no comment.