

5.14 BUPRENORPHINE + NALOXONE

4mg/1mg film: sublingual, 12mg/3mg film: sublingual, Suboxone[®] sublingual film; Reckitt Benckiser Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission seeks to list two additional strengths of buprenorphine + naloxone to allow for increased compliance, providing more accurate and flexible dosing and addressing quality use of medicines concerns.

2 Requested listing

- 2.1 The submission requested listing the additional strengths of buprenorphine + naloxone with the same Section 100 listing as the existing strengths.

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

3 Background

- 3.1 Buprenorphine + naloxone 12mg/3mg and 4mg/1mg were TGA registered in April 2014 for the treatment of opiate dependence within a framework of medical, social and psychological treatment.
- 3.2 Buprenorphine + naloxone 8mg/2mg and 2mg/0.5mg were recommended for PBS listing at the November 2005 PBAC meeting for the treatment of opiate dependence, within a framework of medical, social and psychological treatment. The 12mg/3mg and 4mg/1mg strengths have not previously been considered by the PBAC.

4 Clinical place for the proposed therapy

- 4.1 The submission states that the introduction of two additional strengths of buprenorphine + naloxone will provide significantly greater flexibility in dosing options to healthcare professionals and patients, while also expecting to improve compliance to treatment.
- 4.2 Data provided in the submission from the National Drug and Alcohol Research Centre show that the mean daily dose of buprenorphine is 12mg daily. With the currently available strengths, a patient on this dose would be required to use one 8mg/2mg film and two 2mg/0.5mg films.
- 4.3 The availability of additional strengths intends to address quality use of medicines issues surrounding the current practice of patients placing more than the recommended two films at a time on the sublingual mucosa, or placing films onto other parts of the buccal mucosa, in order to shorten administration time when patients are on doses that require more than two films.

- 4.4 Clinician advice was sought from the National Drug and Alcohol Research Centre to clarify the clinical need for the availability of these additional strengths. The advice highlighted that listing additional strengths may decrease the likelihood of diversion, while also potentially leading to benefits for pharmacies in terms of administration time and improve flexibility in dose titration.

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 price proposed was based on 4mg/1mg film replacing the use of two 2mg/0.5mg films and the 12mg/3mg film replacing one 8mg/2mg film and two 2mg/0.5mg films.

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

Estimated PBS usage & financial implications

- 6.4 The listing of additional strengths is intended to be an alternative to currently available strengths and is not expected to affect overall usage.
- 6.5 The submission used a market share approach to estimate the utilisation and cost of the additional strengths over a five year time horizon.

	Year 1	Year 2	Year 3	Year 4	Year 5
Cost of 4mg and 12mg	██████████	██████████	██████████	██████████	██████████
Cost offset – 2mg and 8mg	██████████	██████████	██████████	██████████	██████████
Net cost	██████████	██████████	██████████	██████████	██████████

The redacted table shows the estimated net cost to be less than \$10 million per year.

- 6.6 The net positive difference is likely to be due to higher daily doses (24mg and above) while lower doses are expected to be cost neutral. The Pre-PBAC response (p1) reiterated that, considering that 12mg is the most commonly used dose, it is expected that the true cost of the listing the new strengths of 4 and 12mg is most

likely to be cost neutral. A net positive cost to the PBS could arise if higher daily doses (24mg and above) are used, which the sponsor considered to be an extremely unlikely scenario.

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

7 PBAC Outcome

- 7.1 The PBAC recommended the listing of buprenorphine/naloxone 12mg/3mg and 4mg/1mg under the same conditions as the currently listed strengths.
- 7.2 The PBAC considered there would be a moderate benefit associated with listing additional strengths including a reduced number of films required to be administered to patients, in turn potentially decreasing the risk of diversion, improving pharmacy administration time, and allowing flexibility of dose titration, addressing potential quality use of medicines issues relevant to this product.
- 7.3 The PBAC noted the valuable and extensive input received from the National Drug and Alcohol Research Centre (NDARC) regarding the clinical place for additional strengths of buprenorphine/naloxone.
- 7.4 The PBAC considered that the method used to calculate the proposed price of the new strengths may not be appropriate, and that it may be more appropriate for the price per milligram of the new strengths to be linearly extrapolated from the prices of the currently listed strengths.
- 7.5 The PBAC considered that the nature of substitution at a patient level is uncertain and may potentially result in a different net cost to that proposed in the submission, but that overall, the addition of the new strengths is unlikely to grow the overall market for this product.
- 7.6 Advice to the Minister under Subsection 101 3BA of the National Health Act
In accordance with subsection 101(3BA) of the *National Health Act 1953*, the PBAC advised that it is of the opinion that buprenorphine/naloxone should not be treated as interchangeable on an individual patient basis with any other drug(s).
- 7.7 The PBAC advised that buprenorphine/naloxone is suitable for prescribing by nurse practitioners under a shared care model.
- 7.8 The PBAC recommended that the Safety Net 20 Day Rule should not apply, noting that it currently does not apply to the 8mg/2mg and 2mg/0.5mg strengths.

Outcome:

Recommended

8 Recommended listing

- 8.1 Add new items:

Public Summary Document – November 2014 PBAC Meeting

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
BUPRENORPHINE AND NALOXONE				
Buprenorphine 12mg + naloxone 3mg sublingual, 28 films	1	0	Suboxone®	RB
Buprenorphine 4mg + naloxone 1mg sublingual, 28 films	1	0	Suboxone®	RB

Category / Program	Section 100 – Opiate Addiction Treatment
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
Episodicity:	-
Severity:	-
Condition:	-
PBS Indication:	Opiate dependence
Treatment phase:	-
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
Treatment criteria:	-
Clinical criteria:	The treatment must be within a framework of medical, social and psychological treatment.
Population criteria:	-
Foreword	-
Definitions	-
Prescriber Instructions	-
Administrative Advice	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. Treatment must be in accordance with the law of the relevant State or Territory.

Cautions	Buprenorphine with naloxone soluble film and buprenorphine with naloxone sublingual tablet do not meet all the criteria for bioequivalence. Patients being switched between sublingual tablets and soluble films may therefore require a dosage adjustment.
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- 8.2 Amend restrictions for existing strengths of buprenorphine/naloxone (8mg/2mg and 2mg/0.5mg) from legacy format for consistency between all strengths.

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 had no comment.