

5.28 BUPRENORPHINE

15 microgram/hour patch, 25 microgram/hour patch, 30 microgram/hour patch, 40 microgram/hour patch; Norspan®; Mundipharma Pty Ltd.

1 Purpose of Application

1.1 The minor submission sought to list four additional strengths of buprenorphine. The submission claimed that this would enable effective chronic pain control for patients at more appropriate dosing levels by providing more single patch dosing intervals.

2 Requested listing

2.1 The submission requested listing the additional patch strengths of buprenorphine with the same General Schedule listing as the existing patch strengths: 5 microgram/hour, 10 microgram/hour and 20 microgram/hour.

2.2 The current listing does not comply with electronic media requirements and has been remodelled by the Secretariat.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
BUPRENORPHINE				Norspan® Mundipharma Pty Ltd
15 microgram/hour patch, 2	1	0	\$ [REDACTED]	
25 microgram/hour patch, 2	1	0	\$ [REDACTED]	
30 microgram/hour patch, 2	1	0	\$ [REDACTED]	
40 microgram/hour patch, 2	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-narcotic analgesics.

Administrative Advice	<p>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-narcotic analgesics where the total duration of narcotic 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-narcotic 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 narcotic 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-narcotic 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.

2.3 Expert clinicians have advised that “narcotic” is an outdated term that has been replaced with “opioid” in clinical practice.

3 Background

3.1 The currently-listed buprenorphine transdermal patch strengths were TGA approved in April 2004 for the management of moderate to severe pain. The requested strengths were registered in November 2014.

3.2 The currently-listed buprenorphine transdermal patch strengths were recommended for PBS listing at the July 2005 PBAC meeting for the treatment of chronic severe disabling pain. The requested strengths have not previously been considered by the PBAC.

3.3 In November 2014 the PBAC noted that use of opioids, particularly oxycodone and paracetamol + codeine, is drastically 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.

3.4 In October 2014 the Drug Utilisation Sub-Committee (DUSC) considered a report on the utilisation of PBS-listed opioid analgesics from October 2009 to March 2014. This report included an analysis on the utilisation of buprenorphine by strength and by age. The report found that the utilisation of buprenorphine patches has increased since 2009, that the 5 microgram/hour and 10 microgram/hour patches were the most frequently supplied strengths (while use of the 20 microgram/hour was still highly utilised), and that utilisation was substantially higher in patients aged 70 and older compared with younger age groups. The review also noted that Authority approvals for increased quantities or repeats of buprenorphine accounted for 11.65% of authorities for increased quantities or repeats for all PBS medicines.

- 3.5 The PBAC previously considered the issues relating to opioid subsidy at various times, including at a stakeholder meeting in 2011 and at the August Special PBAC meeting in 2012.

4 Clinical place for the proposed therapy

- 4.1 The submission stated that the introduction of four additional strengths was to allow for improved individual dose titration of buprenorphine, which would avoid unnecessary side effects whilst allowing patients to obtain maximum analgesic benefits.
- 4.2 The submission also contended that the introduction of higher strengths would enable patients requiring higher strengths for their pain management to access this more appropriately. The submission appeared to have used figures from the DUSC report to calculate that 29.4% of buprenorphine scripts are subject to Authority approval for increased quantities or repeats.
- 4.3 The submission claimed, based on the DUSC report, that there was significant use in the 10 µg/h and 20 µg/h patches. The submission asserted that this would support the clinical need for an intermediate dose, stating that a 15 µg/h patch would allow for more flexible titration with smaller increments.

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 for the new strengths was based on pricing derivation advised by the Pharmaceutical Benefits Pricing Authority manual, where if the new strength is double that of an existing strength it should be priced at one and two-thirds of the existing strength. In line with this methodology, the submission proposes that the 40 microgram/hour patch be priced one and two-thirds of the currently listed 20 microgram/hour patch (calculated at ex-manufacturer price), and the remaining strengths be priced at the midpoint between the next lower and next higher strength (calculated at ex-manufacturer level).

Product	Ex-manufacturer price
buprenorphine 5 microgram/hour patch, 2	\$ [REDACTED] (at February 2014)
buprenorphine 10 microgram/hour patch, 2	\$ [REDACTED] (At February 2014)
<i>buprenorphine 15 microgram/hour patch, 2 proposed price</i>	\$ [REDACTED]
Buprenorphine 20 microgram/hour patch, 2	\$ [REDACTED] (At February 2014)
<i>buprenorphine 25 microgram/hour patch, 2 proposed price</i>	\$ [REDACTED]
<i>buprenorphine 30 microgram/hour patch, 2 proposed price</i>	\$ [REDACTED]
<i>buprenorphine 40 microgram/hour patch, 2 proposed price</i>	\$ [REDACTED]

Estimated PBS usage & financial implications

6.4 The listing of additional strengths was intended to provide an intermediate dosing option which otherwise would have been achieved through the combination of different strength patches. As such, the listing of the additional strengths was 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 using a linear extrapolation over a five year time horizon.

Cost to PBS

	Year 1	Year 2	Year 3	Year 4	Year 5
Volume (PBS Services) – without new presentations	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx
Volume (PBS Services) – with new presentation	[REDACTED] Rx	[REDACTED]	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx
Net volume	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx	[REDACTED] Rx
Cost – without new presentations	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Cost – with new presentations	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
Net Cost	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]

Cost to RPBS

	Year 1	Year 2	Year 3	Year 4	Year 5
Volume (RPBS Services) – without new presentations	█ Rx	█ Rx	█ Rx	█ Rx	█ Rx
Volume (RPBS Services) – with new presentations	█ Rx	█ Rx	█ Rx	█ Rx	█ Rx
Net volume	█ Rx	█ Rx	█ Rx	█ Rx	█ Rx
Cost – without new presentations	\$ █	\$ █	\$ █	\$ █	\$ █
Cost – with new presentations	\$ █	\$ █	\$ █	\$ █	\$ █
Net Cost	-\$ █	-\$ █	-\$ █	-\$ █	-\$ █

6.6 At year 5, the estimated number of PBS scripts was over 200,000 and the net saving to the PBS was estimated to be less than \$10 million.

6.7 The submission predicted that the actual number of PBS/RPBS Services would decline as patients who currently require two patches to achieve an intermediate dose would be prescribed one patch for the same dose. The submission claimed that the savings are driven by the reduced PBS/RPBS co-payment for a single patch compared to two patches to achieve the same dose.

7 PBAC outcome

7.1 The PBAC deferred making a recommendation regarding the proposed General Schedule listing of additional buprenorphine patch strengths.

7.2 The PBAC noted that the requested 40 microgram/hour patch was stronger than the strongest currently listed patch (20 microgram/hour). The PBAC considered that the submission had not explored the risk of utilisation being driven towards higher doses due to the availability of the higher strength patches. The PBAC considered that clarifying this issue would be essential to establish the clinical appropriateness strengths above the current 20 microgram/hour patch.

7.3 The PBAC considered that further advice would need to be sought regarding the clinical place and appropriateness for additional strengths of buprenorphine patches, and recommended that the Department consult with organisations representing physicians experienced in pain management.

7.4 The PBAC noted expert clinician advice that “narcotic” is an outdated term that has been replaced with “opioid” in clinical practice, and agreed 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.

Outcome:
Deferred

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.