

6.07 BUPRENORPHINE

Transdermal patch 5 microgram/hour, 10 microgram/hour, 15 microgram/hour, 20 microgram/hour, 25 microgram/hour, 30 microgram/hour, 40 microgram/hour Norspan®, Mundipharma Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested new listings of all strengths of buprenorphine transdermal patches on the Palliative Care Schedule with a maximum quantity of 4 patches with two repeats, providing up to three months' supply.

2 Requested listing

- 2.1 The submission requested Authority Required (STREAMLINED) listings on the palliative care schedule for all strengths of buprenorphine transdermal patches currently available on the general schedule. Morphine is currently listed on the Palliative Care Schedule for chronic disabling pain. It is an Authority Required listing with one month available by telephone authority and up to three months' supply available by written authority. This is consistent with guidelines for palliative care authority applications for opioids available on the PBS website.
- 2.2 Suggestions and additions proposed by the Secretariat to the requested listing are added in italics.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and
BUPRENORPHINE				Norspan®	Mundipharma Pty Ltd
Transdermal patch 5 microgram/hour, 2	2	2	\$42.36		
Transdermal patch 10 microgram/hour, 2	2	2	\$65.61		
Transdermal patch 15 microgram/hour, 2	2	2	\$79.80		
Transdermal patch 20 microgram/hour, 2	2	2	\$93.99		
Transdermal patch 25 microgram/hour, 2	2	2	\$107.43		
Transdermal patch 30 microgram/hour, 2	2	2	\$120.87		
Transdermal patch 40 microgram/hour, 2	2	2	\$147.75		

Category / Program	GENERAL – General Schedule Palliative Care (Code PL)
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:	Chronic

Severity:	Severe
Condition:	disabling pain
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input checked="" type="checkbox"/> Authority Required – Emergency <input checked="" type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	<i>Patient must be receiving palliative care</i> AND The condition must be unresponsive to non-opioid analgesics
Administrative Advice	<i>Telephone approvals are limited to 1 month's therapy.</i>
Cautions	The risk of drug dependence is high.

- 2.3 The Pre-PBAC response accepted the Secretariat's suggested wording for the restriction.

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

3 Background

- 3.1 Buprenorphine transdermal patches are TGA registered for the management of moderate to severe pain.
- 3.2 Buprenorphine patches were recommended for PBS listing by the PBAC in July 2005 for chronic severe disabling pain which is unresponsive to non-narcotic analgesics. Currently, packs of two patches are available as a restricted benefit listing on the General Schedule with no repeats, sufficient to provide two weeks of therapy, while authorities for increased maximum quantities and/or repeats are able to be granted in certain circumstances.
- 3.3 In November 2015, the PBAC did not recommend an additional Authority Required (STREAMLINED) listing for buprenorphine patches on the general schedule with increased maximum quantity and number of repeats, considering that the current restricted benefit listing for two weeks supply remained appropriate to meet patient needs. The PBAC considered that the requested listing may not be appropriate from a quality use of medicines perspective.
- 3.4 This is the first submission for buprenorphine transdermal patches for listing on the Palliative Care Schedule.

4 Clinical place for the proposed therapy

- 4.1 The submission claimed a Palliative Care Schedule listing with three months' supply will help remove or reduce barriers to effective in-home palliative care, allowing for

palliative care patients to access larger quantities, reducing patient out of pocket costs and prescriber administrative burden.

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 and welcomed the input from a health care professional (1) via the Consumer Comments facility on the PBS website. The comment described the benefits of a streamlined authority listing for buprenorphine for patients in the palliative care setting including more efficient and effective palliative care pain management, reduced need to access pharmacies and general practices and increased ability to treat palliative care patients in rural locations and residential aged care facilities.

Economic analysis

5.3 The submission proposed the same price as the current General Schedule listing based on approved ex-manufacturer price per patch.

Estimated PBS usage & financial implications

5.4 The submission used a market share approach to estimate PBS usage and assumed that up to 7% of current buprenorphine transdermal patch use within the General Schedule listings is for patients receiving palliative care who would instead use the proposed palliative care schedule listings. No evidence was provided in the submission to support this estimate.

5.5 The submission assumed no net change in the number of patients accessing buprenorphine and that patient's current dosing will remain unaltered as a consequence of the proposed listing.

5.6 The submission estimated cost savings to the PBS from fewer dispensing fees, savings to the MBS through reduced GP visits and reduced administrative costs as a result of fewer authority prescriptions processed.

5.7 The submission estimated a cost saving of less than \$10 million in year 5, and a cumulative saving of less than \$10 million over five years. The savings estimated may not be realised and are unable to be verified in a minor submission.

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

6 PBAC Outcome

- 6.1 The PBAC recommended the Authority Required listing of buprenorphine transdermal patches on the Palliative Care Schedule, with a maximum quantity of 4 patches and two repeats.
- 6.2 The PBAC noted that morphine is currently listed on the Palliative Care Schedule for chronic disabling pain. It is an Authority Required listing with one month available by telephone authority and up to three months' supply available by written authority. The PBAC agreed with the Secretariat suggested wording for the restriction, recommending that buprenorphine be aligned with the morphine listing on the Palliative Care Schedule.
- 6.3 The PBAC accepted that there is a clinical need for an increased quantity and number of repeats to be made available for palliative care patients in order to improve access and convenience for patients receiving palliative care.
- 6.4 The PBAC considered that the price of buprenorphine patches on the palliative care schedule should remain the same as the current general schedule listing based on approved ex-manufacturer price per patch.
- 6.5 The PBAC considered that it was unlikely that more patients would use buprenorphine patches as a consequence of the new listing.
- 6.6 The PBAC agreed that the savings calculated in the submission are expected to be nominal and may not be realised.
- 6.7 The PBAC recommended that buprenorphine should not be treated as interchangeable with any other drugs.
- 6.8 The PBAC advised that, as for morphine on the Palliative Care Schedule, buprenorphine is suitable for prescribing by nurse practitioners.
- 6.9 The PBAC noted the Early Supply Rule cannot currently be applied to Palliative Care listings. The PBAC noted it would be appropriate to consider the application of the Early Supply Rule to buprenorphine in the future if listings on the Palliative Care Schedule become eligible.
- 6.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 6.7 Amend existing listing as follows:

Public Summary Document – July 2016 PBAC Meeting

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Transdermal patch	2	2		
25 microgram/hour, 2				
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Transdermal patch	2	2		
40 microgram/hour, 2				

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Clinical criteria:	Patient must be receiving palliative care AND The condition must be unresponsive to non-opioid analgesics
Administrative Advice	Telephone approvals are limited to 1 month's therapy.
Cautions	The risk of drug dependence is high.

7 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.

8 Sponsor's Comment

The sponsor had no comment.