

6.13 BUPRENORPHINE
5 microgram/hour patch, 10 microgram/hour patch,
20microgram/hour patch,
Norspan[®], Mundipharma Pty Ltd

1 Purpose of Application

1.1 The minor submission requested an additional Authority Required (STEAMLINED) listing for buprenorphine with a maximum quantity of 4 patches and 2 repeats for patients who have achieved a stable dose of buprenorphine patches.

2 Requested listing

2.1 The submission requested the following additional purpose be added to the existing listing. The requested restriction has been amended to comply with electronic media requirements. Secretariat suggested changes have been presented in italics below.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
BUPRENORPHINE				
Patch 5 microgram/hour	4	2	\$ [REDACTED]	
Patch 10 microgram/hour	4	2	\$ [REDACTED]	Norspan [®] Mundipharma
Patch 20 microgram/hour	4	2	\$ [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
Episodicity:	Chronic
Severity:	severe
Condition:	disabling pain
PBS Indication:	Chronic severe disabling pain
Treatment phase:	Continuing
Restriction Level / Method:	<input checked="" type="checkbox"/> Streamlined
Treatment criteria:	-
Clinical criteria:	<i>The patient must be stabilised on buprenorphine patches and require ongoing therapy;</i> <i>AND</i> <i>The patient must meet at least one criteria for ongoing treatment;</i> <i>OR</i> <i>Patient must have previously received an authority prescription for this drug</i>

Prescriber Instructions	<p><i>Criteria for ongoing treatment include:</i></p> <ul style="list-style-type: none"> <i>i) Chronic severe disabling pain associated with proven malignancy</i> <i>ii) Chronic severe disabling pain not responding to non-narcotic analgesics where the total duration of narcotic analgesic treatment is less than 12 months</i> <i>iii) Chronic severe disabling pain not responding to non-narcotic analgesics for treatment beyond 12 months 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.</i> <p><i>Where a patient has been reviewed by another medical practitioner, 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 the consultation are to be recorded in the patient's medical records.</i></p>
Administrative Advice	<p>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>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p>
Cautions	<p><i>The risk of drug dependence is high.</i></p>

3 Background

- 3.1 Buprenorphine patches are TGA registered for management of moderate to severe chronic 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 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.

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

- 4.2 The PBAC noted that no consumer comments were received for this item.

Supportive evidence

- 4.3 The submission provided international utilisation studies in order to demonstrate the need for the new requested listing. The submission claimed that following dose stabilisation, many patients receive prolonged treatment with buprenorphine patches at a consistent dose, and these patients would therefore benefit from receiving 1 month’s therapy per prescription. The applicability of these international studies to the PBS population is unclear and were unable to be thoroughly evaluated in the context of a minor submission.
- 4.4 The submission also provided an analysis of Australian GP prescribers to determine the current rate of GP encounters during which buprenorphine is prescribed via an authority prescription. The analysis indicated that an average of [REDACTED] of buprenorphine prescribing is for increased quantities. The methodology of this study was unable to be validated.

Economic analysis

- 4.5 The price proposed for the Authority Required (STREAMLINED) listing based on the equivalent ex-manufacturer price per patch.

Table 1: Proposed price for Authority Required (STREAMLINED) listing

Product	Ex-manufacturer price (qty 2)	Proposed ex-manufacturer price (qty 4)
buprenorphine 5 µg/hour patch	\$ [REDACTED]	\$ [REDACTED]
buprenorphine 10 µg/hour patch	\$ [REDACTED]	\$ [REDACTED]
Buprenorphine 20 µg/hour patch	\$ [REDACTED]	\$ [REDACTED]

Source: Table 11, p40 of the minor submission

Estimated PBS usage & financial implications

- 4.6 The submission used a market share approach to estimate the use and financial implications of the proposed listing. The submission assumed that [REDACTED] of patients currently granted authority prescriptions for increased quantities and [REDACTED] of patients currently granted authority prescriptions for increased repeats will be eligible under the new restriction, while [REDACTED] of patients receiving 2 patches under the current restricted benefit listing will be prescribed buprenorphine patches under the proposed restriction.
- 4.7 The submission predicted that there will be no net change in the number of patients seeking buprenorphine as a result of the new listing, and that a patient’s current dosing regimen will remain the same. The submission proposed that savings will be generated through reduced dispensing fees, GP consultations and costs associated with processing authority prescriptions. The assumptions used to estimate financial implications of the new listing were not evaluated in the context of a minor submission and the magnitude of these savings may not be realised.

5 PBAC Outcome

- 5.1 The PBAC did not recommend an additional Authority Required (STREAMLINED) listing for buprenorphine patches with increased maximum quantity and number of repeats, considering that the current restriction level remains appropriate to meet

patient needs.

- 5.2 The PBAC noted its recommendation to list additional buprenorphine patch strengths, considering that the availability of higher strength patches may address the need for prescribers to request increased quantities by telephone for patients who use two patches concurrently to achieve the desired dose.
- 5.3 The PBAC considered that while the proposed listing may reduce regulatory burden, the pain treatment algorithm remains unclear and there may be a risk of prescribing the patches to a broader patient population than intended in the restriction. The PBAC therefore considered that the requested listing may not be appropriate from a quality use of medicines perspective.
- 5.4 The PBAC noted that increasing access to opioids may be of concern to State and Territories, and that any future consideration for increasing the quantity and/or repeats of opioids should be done in consultation with States and Territories.

Outcome:

Rejected

6 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.

7 Sponsor's Comment

The Sponsor will continue to work with the PBAC and other stakeholders to ensure continued quality use of medicines and that patients have access to treatments to control chronic severe disabling pain in quantities appropriate to their needs.