

**4.01 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 patches under the same conditions as the currently listed strengths.

**2 Requested listing**

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

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]	

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Chronic severe disabling pain
<b>PBS Indication:</b>	Chronic severe disabling pain
<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	The condition must be unresponsive to non-narcotic analgesics.

<p><b>Administrative Advice</b></p>	<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>
<p><b>Cautions</b></p>	<p>The risk of drug dependence is high.</p>

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 At the March 2015 PBAC meeting, the PBAC deferred making a recommendation regarding the proposed general schedule listing of additional strengths of buprenorphine patches and considered that further advice would need to be sought regarding their clinical place and appropriateness. The PBAC recommended that the Department consult with organisations representing physicians experienced in pain management.

3.2 The Department sought advice from the following organisations:

- Faculty of Pain Medicine
- Australian College of Rural and Remote Medicine
- Australian Pain Society
- National Drug and Alcohol Research Centre
- Royal Australasian College of Physicians (Australasian Chapter of Addiction Medicine)

3.3 Responses were received from the Faculty of Pain Medicine, Australian Pain Society, National Drug and Alcohol Research Centre and the Royal Australasian College of Physicians.

3.4 With regards to clinical need for higher strength buprenorphine patches, the responses concurred that the availability of higher strengths would be in line with clinical and pharmacological literature. It was noted that some addiction medicine specialists currently prescribe the concurrent use of two 20 microgram/hour buprenorphine patches to reach the desired dose. The safety profile of

buprenorphine at high doses compared with other opioids was also emphasised. It was stated that 40 microgram/hour buprenorphine patches would allow for improved analgesic efficacy, reduced development of opioid-induced hyperalgesia and tolerance, and reduced use of full-strength opioids. It was also considered that less dose escalation would be expected compared with other opioids.

- 3.5 In July 2015, the PBAC reconsidered the submission in light of expert opinion received. The PBAC noted that while the responses were in general agreement that there was a clinical place for additional strengths of buprenorphine, it was not clear which additional strengths would be the most appropriate. The PBAC deferred making a recommendation to list additional patch strengths at this time.

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

#### **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.

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

#### **5 PBAC outcome**

- 5.1 The PBAC recommended the general schedule listing of buprenorphine 15 microgram/hour patch, 25 microgram/hour patch, 30 microgram/hour patch and 40 microgram/hour patch, under the same conditions as the currently listed strengths.
- 5.2 The PBAC noted the advice from the organisations representing physicians experienced in pain management.
- 5.3 The PBAC considered there may be a moderate benefit associated with listing additional strengths of buprenorphine patches including improved analgesic efficacy and flexibility of dose titration.
- 5.4 In accordance with subsection 101 (3BA) of the *National Health Act* 1953, the PBAC advised that it is of the opinion that buprenorphine should not be treated as interchangeable on an individual patient basis with any other drug.
- 5.5 The PBAC advised that as for existing strengths, new strengths of buprenorphine patches are suitable for prescribing by nurse practitioners under a shared care model.
- 5.6 The PBAC recommended that the Safety Net 20 Day rule should not apply, as it currently does not apply to the existing strengths.

#### **Outcome:**

Recommended

**6 Recommended listing**

6.1 Add new items:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
BUPRENORPHINE			Norspan®	Mundipharma Pty Ltd
15 microgram/hour patch, 2	1	0		
25 microgram/hour patch, 2	1	0		
30 microgram/hour patch, 2	1	0		
40 microgram/hour patch, 2	1	0		

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Chronic severe disabling pain
<b>PBS Indication:</b>	Chronic severe disabling pain
<b>Restriction Level / Method:</b>	<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
<b>Clinical criteria:</b>	The condition must be unresponsive to non-narcotic analgesics.
<b>Administrative Advice</b>	<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>
<b>Cautions</b>	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 welcomes the PBAC's decision and will be working towards ensuring that patients have access to a broader choice of treatments to control chronic severe disabling pain.