

## **5.19 BACLOFEN**

### **Intrathecal injection 40 mg in 20 mL, Sintetica Baclofen Intrathecal<sup>®</sup>, Boucher & Muir Pty Ltd**

#### **1 Purpose of Application**

- 1.1 The minor submission requested a Section 100 Highly Specialised Drugs (HSD) Public Hospital Authority Required (STREAMLINED) listing and a Section 100 HSD Private Hospital Authority Required listing of a new strength of baclofen (40 mg in 20 ml ampoule) for the treatment of severe chronic spasticity, the same indication as the currently listed 10 mg/ 5 mL ampoules.

#### **2 Requested listing**

- 2.1 The submission requested the same restriction as for the currently listed form of baclofen, for the treatment of severe chronic spasticity of cerebral origin, due to multiple sclerosis, due to spinal cord injury, or due to spinal cord disease.

#### **3 Background**

- 3.1 Baclofen 40 mg/20 mL ampoule was TGA registered in March 2017 for patients with severe chronic spasticity of spinal origin (associated with injury, multiple sclerosis, or other spinal cord diseases) or of cerebral origin who are unresponsive to orally administered antispastics (including oral baclofen) and/or who experience unacceptable side effects at effective oral doses.
- 3.2 Baclofen 10 mg/5 mL and 10 mg/20 mL were recommended by the PBAC in June 2000. Baclofen 10 mg/20 mL was deleted from the PBS in August 2008.
- 3.3 Baclofen intrathecal injection 40 mg/20 mL ampoule has not been previously considered by the PBAC.
- 3.4 A generic brand of baclofen 10 mg/5 mL with a pack size of 10 from the same sponsor (Boucher & Muir Pty Ltd) was listed on the PBS from 1 June 2017 under the same restriction as the 10 mg/5 mL single ampoules.

## 4 Current situation

- 4.1 The submission stated that baclofen is delivered to a patient via an implantable intrathecal pump. The reservoir is either 20 mL or 40 mL in size, and therefore requires multiple 10 mg/5 mL baclofen ampoules to be combined into a single syringe in laminar flow. The submission contended that the 20 mg/40 mL form will reduce potential patient and provider safety risks and has advantages in ease of preparation.
- 4.2 The submission also stated that because the contents of the reservoir can last between one and six months, depending on dosing, the longer in-situ life of the 40 mg/20 mL form (180 days compared to 77 days) has additional advantages for patients and offered potential reduction in wastage.

## 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 that no consumer comments were received for this item.

### *Estimated PBS usage & financial implications*

- 5.3 The submission proposed an equivalent price per milligram (AEMP) for the 40 mg/20 mL ampoule relative to the currently listed 10 mg/5 mL ampoule, which results in a proposed AEMP of \$498.52 and DPMQ of \$997.04 for Section 100 Public Hospital, and \$1,043.94 for Section 100 Private Hospital.
- 5.4 The submission estimated the financial impact of listing the proposed 40 mg/20 mL ampoule using a market share approach and utilisation data (Medicare PBS statistics and IMS data).
- 5.5 The submission assumed that there was no growth in the utilisation of baclofen for the next six years. However, the forecast included in the financial estimates based on PBS script data predicts a small increase in script numbers of approximately 4% per year. The pre-PBAC response (p2) acknowledged this increase, and stated that the effect of the increase market size was modelled in the submission's sensitivity analysis, which indicated that this would have limited financial impact.

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- 5.6 The submission assumed that 75% of the currently listed 10 mg/5 mL market will be displaced by the new 40 mg/20 mL ampoule, and estimated a substitution rate of ■■■ scripts for the 40 mg/20 mL ampoule for every prior script of the 10 mg/5 mL ampoule. This approach assumed that all patients were accessing the full maximum quantity of the currently available form (100 mg per script), and that there would therefore be additional scripts on the basis of the lower maximum quantity available (80 mg per script). This is unlikely because the volume of the infusion device is 20 or 40 mL, which would mean most patients are not accessing the currently available maximum quantity (which is a volume of 50 mL). In the event that patients require more than 80 mg, they may still choose to access the 10 mg/5 mL form because it will mean one co-payment instead of two. The pre-PBAC response did not adequately justify the argument that there would be cost savings to government due to an increase in the number of co-payments.
- 5.7 Furthermore, the submission's assumption that 25% of patients would continue using the 10 mg/5 mL form because they are using smaller amounts was in contradiction with their claim that the minimum amount that can be put in an infusion pump is 20 mL.
- 5.8 A review of the PBS dispensing patterns in 2016 showed that most patients received 20, 40 or 80mg per dispensing (■■■% of scripts). Based on this dispensing pattern, approximately ■■■% of patients could move to the new strength with no requirement for additional scripts or increased quantities, with ■■■% of patients needing to remain on the currently listed strength to avoid additional wastage.
- 5.9 The Secretariat noted that based on the current dispensing data, there is a potential risk of wastage for the generic brand of baclofen 10 mg/5 mL with a pack size of 10 (item 11126N and 11128Q) as only ■■■ per cent of patients were dispensed 100 mg.
- 5.10 The submission estimated a saving of less than \$10 million over the first five years of listing, due to an increase in the number of patient co-payments. The PBAC considered that it does not seem reasonable to assume an increase in patient co-payments, and therefore it is unlikely that this saving will be realised.

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Table 1: Estimated net saving to the PBS/RPBS associated with listing a 40 mg/20 mL baclofen intrathecal injection ampoule

	Year 1	Year 2	Year 3	Year 4	Year 5	Total Cost
<b>Projected net cost of new listing</b>						
PBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
<b>Projected net costs of displaced medicines</b>						
PBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
PBS/RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
<b>Overall net cost to the PBS/RPBS</b>						
PBS	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]
RPBS	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]	\$ [REDACTED]
PBS/RPBS	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]	-\$ [REDACTED]

Source: Section 4 Workbook, 5a. Cost to PBS & RPBS Worksheet

## 6 PBAC Outcome

- 6.1 The PBAC recommended the Section 100 HSD Public Hospital Authority Required (STREAMLINED) listing and a Section 100 HSD Private Hospital Authority Required listing of a new strength of baclofen (40 mg in 20 mL ampoule), with the same indication as the currently listed 10 mg in 5 mL ampoules (the treatment of severe chronic spasticity), at an equivalent price per milligram as the current listing.
- 6.2 The submission requested a maximum quantity of two ampoules, totalling 80 mg in 40 mL with each prescription. The Secretariat noted that this is less than the existing listing of baclofen 10 mg/5mL that allows for a maximum quantity of 100 mg. The PBAC noted that the requested maximum quantity is consistent with the intrathecal pump volume used for delivering baclofen, and therefore considered the request was clinically appropriate.
- 6.3 The PBAC noted that the Early Supply Rule is not currently applied to baclofen due to the variable dosing regimen. The PBAC considered that it is appropriate to maintain this existing arrangement.
- 6.4 The PBAC noted that baclofen is listed under Section 100 Highly Specialised Drugs Program, and is currently out of scope of Nurse Practitioner Prescribing.
- 6.5 The PBAC noted that this submission is not eligible for Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

**7 Recommended listing**

Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
BACLOFEN intrathecal injection, 40mg /20 mL ampoule	2	0	Sintetica Baclofen Intrathecal	Boucher and Muir Pty Ltd

<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program (Public Hospital)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Severe chronic spasticity
<b>PBS Indication:</b>	Severe chronic spasticity
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity of cerebral origin.

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Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
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<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program (Public Hospital)
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<b>Condition:</b>	Severe chronic spasticity
<b>PBS Indication:</b>	Severe chronic spasticity
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity due to multiple sclerosis.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
BACLOFEN intrathecal injection, 40mg /20 mL ampoule	2	0	Sintetica Baclofen Intrathecal	Boucher and Muir Pty Ltd

<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program (Public Hospital)
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<b>PBS Indication:</b>	Severe chronic spasticity
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity due to spinal cord injury.

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<b>Condition:</b>	Severe chronic spasticity
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<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity due to spinal cord disease.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
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<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program (Private Hospital)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Severe chronic spasticity
<b>PBS Indication:</b>	Severe chronic spasticity
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity of cerebral origin.

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<b>Condition:</b>	Severe chronic spasticity
<b>PBS Indication:</b>	Severe chronic spasticity
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone
<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity due to multiple sclerosis.

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<b>Clinical criteria:</b>	Patient must have failed to respond to treatment with oral antispastic agents; OR Patient must have had unacceptable side effects to treatment with oral antispastic agents, AND Patient must have chronic spasticity due to spinal cord disease.

## 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.