

5.09 BENZATHINE BENZYL PENICILLIN

Injection 517 mg in 1.17 mL single use pre-filled syringe

Bicillin L-A®, Pfizer Australia Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested a General Schedule PBS listing of a new additional strength (0.6 million units (517 mg) in 1.17 mL pre-filled syringe) of the currently listed benzathine benzylpenicillin, (Bicillin L-A®) injection.

2 Requested listing

- 2.1 The submission sought the same listing as the currently listed 1.2 million units (900 mg) in 2.3 mL pre-filled syringe, with an equivalent price per unit. The requested listing is summarised below:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
BENZATHINE BENZYL PENICILLIN 0.6 million units (517 mg)/1.17 mL injection, 10 × 1.17 mL	1	0	\$153.12	Bicillin L-A® Pfizer Australia Pty Ltd
Category / Program	GENERAL – General Schedule (Code GE)			
Prescriber type:	<input checked="" type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives			

3 Background

- 3.1 Benzathine benzylpenicillin 0.6 million units (517 mg) in 1.17 mL injection was TGA registered on 19 September 2018 for the treatment of infections due to penicillin-sensitive micro-organisms that are susceptible to the low and very prolonged serum levels common to this particular dosage form.

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.

Clinical trials

- 4.3 As a minor submission, no clinical trials were presented in the submission.

Estimated PBS usage & financial implications

- 4.4 The minor submission estimated there would be no significant change to the overall usage of benzathine benzylpenicillin on the PBS if the additional strength were listed. The new strength of the drug will provide half of the active ingredient per script compared to the currently listed strength, and therefore result in a reduction in wastage when used for younger patients and a potential saving to the PBS. The sponsor estimated the new strength of Bicillin L-A will replace approximately 5% of prescriptions for the currently listed strength. The PBAC noted the estimated level of uptake and considered that was reasonable.
- 4.5 The sponsor estimated a potential cost saving to the Commonwealth but did not take into consideration the different costs between PBS and RPBS scripts. The Department revised the costings based on Medicare statistics between November 2017 and October 2018. Both the costings estimated in the submission and Department revised numbers are summarised below:

Table 1: estimated cost/saving for the new strength of benzathine benzylpenicillin

		Submission estimates	Department revised estimates
A	Number of prescriptions dispensed of Bicillin L-A 1,200,000 units in 2.3 mL per year (PBS statistics November 2017 to October 2018)		
B	Cost to Commonwealth per year	\$ [redacted] (A x C)	\$ [redacted] (Medicare statistics)
C	Price of Bicillin L-A 1,200,000 units in 2.3 mL	\$298.51 (DPMQ)	\$ [redacted] (B / A)
D	Estimated number of Bicillin L-A 600,000 units prescriptions to replace Bicillin L-A 1,200,000 units prescriptions (A x 5%)		
E	Price of Bicillin L-A 600,000 units in 1.17 mL (proposed DPMQ)		\$ [redacted]
F	Estimated cost of listing Bicillin L-A 600,000 units in 1.17 mL (D x E)		\$ [redacted]
G	Cost of currently listed Bicillin L-A 1,200,000 units if new strength is listed [C x (A – D)]	\$ [redacted]	\$ [redacted]
H	Revised estimated cost to Commonwealth (F + G)	\$1 [redacted] (Calculated by the Department to be \$ [redacted])	\$ [redacted]
	Cost savings to the Commonwealth (B – H)	\$ [redacted] (Calculated by the Department to be \$ [redacted])	\$ [redacted]

Source: page 3 of the submission

The redacted table shows that the estimated number of prescriptions for Bicillin L-A 600,000 units replacing those for Bicillin L-A 1,200,000 units was less than 10,000 and the net cost saving to the Commonwealth would be less than \$10 million.

5 PBAC Outcome

- 5.1 The PBAC recommended the unrestricted General Schedule listing of a new additional strength of benzathine benzylpenicillin (0.6 million units, 517 mg in 1.17 mL pre-filled syringe, Bicillin L-A®) at an equivalent price per unit to the currently listed strength.
- 5.2 The PBAC noted that the new strength contains half the active ingredient of the currently listed strength (0.6 million units compared to 1.2 million units), which is within the TGA-approved dosage for young children: 0.3 million to 0.6 million units per injection. The submission stated the new strength of benzathine benzylpenicillin allows accurate administration of paediatric doses and will reduce wastage.
- 5.3 The PBAC advised that the new strength of benzathine benzylpenicillin should be available for prescribing by medical practitioners, nurse practitioners and dentists, consistent with the existing listing.

- 5.4 The PBAC advised that the Early Supply Rule should not apply as it currently does not apply for the other form of benzathine benzylpenicillin.
- 5.5 The PBAC advised that this submission would not meet the criteria for an Independent Review as it received a positive PBAC recommendation.

Outcome:

Recommended

6 Recommended listing

Add new item:

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BENZATHINE BENZYL PENICILLIN 0.6 million units (517 mg)/1.17 mL injection, 10 × 1.17 mL	1	0	Bicillin L-A®	Pfizer Australia Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input checked="" type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input checked="" type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives

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.