

**5.14 BORTEZOMIB**  
**vial, 3 mg,**  
**Velcade®, Janssen-Cilag Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The minor submission sought listing of a new strength of bortezomib 3mg vial for the same indications as the existing 1 mg and 3.5 mg vials.

**2 Requested listing**

- 2.1 Bortezomib is listed under the Section 100 Efficient Funding of Chemotherapy (EFC) arrangements with different vial presentations subsidised for relapsed refractory (RR) multiple myeloma and re-treatment (3.5mg vials) and newly diagnosed patients (1mg vials).
- 2.2 The submission sought to list the 3 mg strength for both populations:
- Newly diagnosed patients (Ineligible for high dose chemotherapy and Eligible for high dose chemotherapy and autologous stem cell transplantation).
  - Patients with relapsed refractory disease and patients being re-treated.
- 2.3 No changes to the wording of the current bortezomib restrictions were proposed.

**3 Background**

- 3.1 The drug bortezomib is TGA registered for: previously untreated multiple myeloma patients who are not candidates for high dose chemotherapy; for induction therapy prior to high dose chemotherapy with autologous stem cell rescue for patients under 65 years of age with previously untreated multiple myeloma; for the treatment of multiple myeloma patients who have received at least one prior therapy, and who have progressive disease; and for the treatment of adult patients with previously untreated mantle cell lymphoma. Mantle cell lymphoma is not currently subsidised by the PBS.
- 3.2 The PBAC has previously consider bortezomib for the treatment of multiple myeloma in March 2006, July 2007, March 2009, July 2009, March 2011, July 2011, March 2012 and July 2012
- 3.3 The currently listed strengths were listed on the PBS on 1 November 2007 for the treatment of relapsed refractory (RR) disease. The PBS listing was expanded to include re-treatment in March 2011 and newly diagnosed multiple myeloma in October 2012.
- 3.4 The PBS listing of bortezomib is subject to [REDACTED] Deeds of Agreement. [REDACTED]  
[REDACTED].

**4 Clinical place for the proposed therapy**

4.1 Based upon information presented in the DUSC Review of multiple myeloma in October 2013, [REDACTED] % of supplied prescriptions were for doses of 3 mg or less (i.e. BSA  $\leq 1.54\text{m}^2$ ). The submission claims that the presentation of a 3 mg vial would reduce waste and improve efficiency.

**5 Comparator**

5.1 As a minor submission, there was no economic comparison.

**6 Consideration of the evidence**

***Sponsor hearing***

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

***Consumer comments***

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

***Clinical trials***

6.3 As a minor submission, no new clinical trials were presented in the submission.

***Economic analysis***

6.4 As a minor submission, there was no economic comparison presented.

***Estimated PBS usage & financial implications***

6.5 The minor submission proposes the same Approved Ex-Manufacturer Price (AEMP) per milligram to apply for listing the 3 mg vial. The minor submission estimated there to be no financial implications to the PBS or changes in PBS usage as the submission expects the 3 mg vial to substitute for the 3.5 mg vial and have proposed a new Special Pricing Agreement (SPA) for RR and re-treatment and substitute for the 1 mg vial in the newly diagnosed multiple myeloma settings. [REDACTED]

6.6 [REDACTED]

With the F1 5% Statutory Price Reduction (1 April 2016), the pre-PBAC response updated the SPA rebate to % which results in an unchanged net average Commonwealth payment per dispensing (\$) as shown in Table 1 below.

Table 1: Proposed PBS pricing for RR and re-treatment (with and without the F1 5% Statutory Price Reduction)

	Current PBS structure	Proposed PBS listing
Vial size	3.5 mg	3 mg
Approved Ex-Manufacturer Price (AEMP)	\$	\$
Dispensed price (Private)	\$	\$
Proportion of private use (%)	%	%
Dispensed price (Public)	\$	\$
Proportion of public use (%)	%	1%
Average co-pay	\$	\$
Average Commonwealth payment (less co-payment)	\$	\$
Current SPA Rebate (%)	%	N/A
Average Net Commonwealth payment per service [A]	\$	N/A
<b>If 3 mg vial is available for RR and re-treatment</b>		
Proportion of PBS claims	%	%
Weighted average Commonwealth payment per service (less co-payment) [B]	\$	\$
Proposed SPA rebate (%) $[(1-(A/B)) \times 100] = [C]$	%	%
Average Net Commonwealth payment per service $[B \times (1-C)]$	\$	\$

Table 4 of the minor submission

6.7 The minor submission claims there is no net impact to the Commonwealth expected from this proposal.

**7 PBAC Outcome**

7.1 The PBAC recommended the Authority Required Section 100 EFC listing of the new 3 mg vial strength of bortezomib for all currently reimbursed indications of bortezomib for the treatment of multiple myeloma, with the same listing conditions.

7.2 The PBAC noted that 3,000 micrograms was the maximum amount for all listings of bortezomib and that, as it is funded in the Section 100 EFC program, the listing of the 3 mg vial will not impact patients seeking treatment and there would be no change the cost-effectiveness of bortezomib on the PBS. The PBAC noted the Deeds of Agreement between the sponsor and the Department and considered the cost to the Government for the listing of the 3 mg vial should not be greater than current expenditure on bortezemib.

- 7.3 The PBAC noted that the current Authority Required Section 100 EFC listing of the 1 mg vial strength of bortezomib for previously untreated multiple myeloma is subject to a [REDACTED] arrangement. The PBAC therefore considered that where the new bortezomib 3 mg vial is made available through the PBS for previously untreated multiple myeloma, the utilisation of the 3 mg vial should be captured under the existing Risk Sharing Arrangement with [REDACTED], in a way that can be implemented and managed by the Department. This would ensure that the total cost to the Commonwealth does not increase.
- 7.4 The PBAC further noted that it would improve access if all available vial strengths of bortezomib to be considered for a broader listing with the indication ‘multiple myeloma’, potentially allowing for bortezomib to be supplied as Authority Required (STREAMLINED) benefit. However, the PBAC advised this was not appropriate with the current pricing and Deed arrangements. The PBAC would welcome a future pricing proposal from the sponsor that offered a single per mg price for all bortezomib strengths across all indications.

**Outcome:**

Recommended

**8 Recommended listing**

- 8.1 Amend following PBS items 4403Q, 4429D, 4732C, 4706Q, 4712B, 4712B, 4725Q (Public) and 7238Y, 7274W, 7275X, 7268M, 7269N, 7271Q, 7272R (Private) to include ‘bortezomib 3 mg injection, 1 x 3 mg vial’

**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.