

**6.16 BORTEZOMIB,  
Powder for injection 1 mg  
Powder for injection 2.5 mg  
Powder for injection 3.0 mg  
Powder for injection 3.5 mg,  
DBL Bortezomib<sup>®</sup>,  
Pfizer Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The Committee Secretariat submission requested a Section 100 (Efficient Funding of Chemotherapy Program (EFC)) listing of:
- (i) a new vial size containing 2.5 mg of bortezomib, and
  - (ii) the addition of a new brand DBL Bortezomib<sup>®</sup> for existing vial sizes containing 1 mg, 3 mg and 3.5 mg of bortezomib under the same circumstances as the current bortezomib 1 mg, 3 mg and 3.5 mg listings.
- 1.2 Only the request to list a new vial size containing 2.5 mg of bortezomib required consideration by the PBAC.
- 1.3 The request to add a new brand of bortezomib 1 mg, 3 mg and 3.5 mg did not require PBAC consideration.

**2 Background**

- 2.1 Bortezomib is currently listed on the Pharmaceutical Benefits Scheme (PBS) as a Restricted Benefit listing for multiple myeloma.
- 2.2 EFC medicines are governed by the National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 and subsection 33(2) allows substitution of brands with the same chemotherapy drug.
- 2.3 Bortezomib Juno<sup>®</sup> 2.5 mg (sponsored by Juno Pharmaceuticals) was considered for listing for the same purpose as this submission at this same PBAC meeting (item 6.15 refers).

***Registration status***

- 2.4 DBL Bortezomib was listed on the ARTG on 3 November 2017.
- 2.5 DBL Bortezomib is TGA approved for the following indications (Product Information (PI), p1):

- a. in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma who are not candidates for high dose chemotherapy.
- b. as part of combination therapy, treatment of induction therapy prior to high dose chemotherapy with autologous stem cell rescue for patients under 65 years of age with previously untreated multiple myeloma.
- c. treatment of multiple myeloma patients who have received at least one prior therapy, and who have progressive disease.
- d. in combination with rituximab, cyclophosphamide, doxorubicin and prednisone is indicated for the treatment of adult patients with previously untreated mantle cell lymphoma.

### 3 Requested listing

3.1 The submission requested that DBL Bortezomib be listed under the same restriction criteria as Velcade (12219D, 12227M). The submission proposed no changes to the existing restriction.

3.2 The new trade product additions are shown in italics.

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
BORTIZOMIB Injection	12227M (Public) 12219D (Private)	3000 mcg	15
<b>Available brands</b>			
<i>DBL Bortezomib (bortezomib 2.5 mg injection, 1 vial)</i>			
Velcade (bortezomib 1 mg injection, 1 vial)			
Velcade (bortezomib 3 mg injection, 1 vial)			
Velcade (bortezomib 3.5 mg injection, 1 vial)			
Bortezomib Juno (bortezomib 1.0 mg injection, 1 vial)			
Bortezomib Juno (bortezomib 3.5 mg injection, 1 vial)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Restricted benefit			
<b>Indication:</b> Multiple myeloma			

For more detail on PBAC's view, see section 6 PBAC outcome.

## 4 Consideration of the evidence

- 4.1 The TGA considered DBL Bortezomib 1 mg to be bioequivalent to currently listed bortezomib, Velcade 1 mg.
- 4.2 The submission stated that the 2.5 mg vial presentation was developed based on considerations of market requirements and did not pose any safety or efficacy concerns. The submission stated this is because the concentration per millilitre of active ingredient on reconstitution remains the same as the 1.0 mg, 3.0 mg and 3.5 mg vial presentations of the PBS-listed reference brand, Velcade.

### **Sponsor hearing**

- 4.3 There was no hearing for this item.

### **Consumer comments**

- 4.4 The PBAC noted and welcomed the input from individuals (10) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with bortezomib including increased life expectancy. No specific comments were received for the 2.5 mg vial size.

For more detail on PBAC's view, see section 6 PBAC outcome.

## 5 Estimated PBS utilisation and financial implications

- 5.1 The submission did not provide any estimated financial implications to the PBS. It is expected that the most likely candidates to use the 2.5 mg are patients who require between 2 mg and 2.5 mg. In 2020, this was 20,559 supplies out of a total of 46,912 supplies (i.e. 43.82%) based on PBS data.
- 5.2 The requested AEMP (\$576.35) was based on the AEMP of Velcade in March 2021. The submission stated that the proposed AEMP for the 2.5 mg strength had been calculated based on the same price per mg of bortezomib.
- 5.3 Although not a matter for PBAC, the submission acknowledged that, under section 99ACB of the *National Health Act 1953*, the first new brand statutory price reduction will be applied to the bortezomib AEMP at the time of PBS listing of another bortezomib brand. A first new brand reduction was applied to bortezomib on 1 June 2021.

For more detail on PBAC's view, see section 6 PBAC outcome.

## 6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a new vial size containing 2.5 mg of bortezomib as a Section 100 Efficient Funding of Chemotherapy program benefit under the same circumstances of use applying to bortezomib powder for injection 1 mg, 3 mg and 3.5 mg.
- 6.2 The PBAC considered the proposed price of bortezomib 2.5 mg, which was based on the same price per mg as the currently listed 1mg, was appropriate.
- 6.3 The PBAC noted the submission did not provide any estimated financial implications to the PBS. The PBAC considered the most likely candidates to use the 2.5 mg are patients who require a bortezomib dose in the range of between 2 mg and 2.5 mg. Using this assumption and bortezomib utilisation data from 2020, the 2.5 mg is estimated to replace approximately 44% of supplies of the existing bortezomib market.
- 6.4 The PBAC noted that EFC medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011*, and that Section 33(2) allows substitution of brands under the same item code.
- 6.5 The PBAC advised that because bortezomib 2.5 mg is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over currently listed form of bortezomib, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009* for Pricing Pathway A were not met.
- 6.6 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

**Outcome:**

Recommended

## 7 Recommended listing

7.1 Add new medicinal product pack (bortezomib 2.5 mg injection, 1 vial) as follows:

7.2 Add brand (DBL Bortezomib) with the 1 mg, 3 mg and 3.5 mg strengths as follows:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
BORTIZOMIB Injection	12227M (Public) 12219D (Private)	3000 mcg	15
<b>Available brands</b>			
<i>DBL Bortezomib (bortezomib 2.5 mg injection, 1 vial)</i>			
Velcade (bortezomib 1 mg injection, 1 vial)			
Velcade (bortezomib 3 mg injection, 1 vial)			
Velcade (bortezomib 3.5 mg injection, 1 vial)			
Bortezomib Juno (bortezomib 1.0 mg injection, 1 vial)			
Bortezomib Juno (bortezomib 3.5 mg injection, 1 vial)			
<b>Restriction Summary 11099 / Treatment of Concept: 11099</b> (current as at 1 July 2021)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input type="checkbox"/> Restricted benefit			
<b>Indication:</b> Multiple myeloma			

***This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## 8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available

through the PBS. The PBAC welcomes applications containing new information at any time.

## **9 Sponsor's Comment**

The sponsor had no comment.