

**6.15 BORTEZOMIB,
Powder for injection 2.5 mg,
Bortezomib Juno[®],
Juno Pharmaceuticals Pty Ltd**

1 Purpose of Application

- 1.1 The Committee Secretariat submission requested a Section 100 (Efficient Funding of Chemotherapy Program (EFC)) listing of a new vial size containing 2.5 mg of bortezomib under the same circumstances as the current bortezomib 1 mg, 3 mg and 3.5 mg listings.

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 DBL Bortezomib[®] 2.5 mg (sponsored by Pfizer) was considered for listing for the same purpose as this application at this same PBAC meeting (item 6.16 refers).

Registration status

- 2.4 Bortezomib Juno was listed on the ARTG on 2 October 2019.
- 2.5 Bortezomib Juno 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 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.
 - c. for 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 for the treatment of adult patients with previously untreated mantle cell lymphoma.

3 Requested listing

- 3.1 The submission requested listing of Bortezomib Juno 2.5 mg injection under the same circumstances as bortezomib 1 mg, 3 mg and 3.5 mg injections. The sponsor does not have a 3 mg injection currently listed on the PBS and does not propose listing this strength in this submission.
- 3.2 The new trade product is shown in *italics*.

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

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

4 Consideration of the evidence

- 4.1 The TGA considered Bortezomib Juno 1 mg and 3.5 mg to be bioequivalent to the currently listed brand of bortezomib, Velcade 1 mg and 3.5 mg.
- 4.2 The submission stated that as the 2.5 mg strength is not listed on the PBS, no reference in terms of bioequivalence has been made. However, given linearity in pharmacokinetics and that a strength of 2.5 mg lies in within the range already considered by the PBAC, there was no additional clinical or safety data that needed consideration.

- 4.3 The submission claimed that the 2.5 mg strength would reduce waste and improve efficiency in dose preparation.

Sponsor hearing

- 4.4 There was no hearing for this item.

Consumer comments

- 4.5 The PBAC noted and welcomed the input from individuals (11) via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with bortezomib including increased life expectancy, fewer side effects and improved quality of life. 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 used a market-share approach to estimate the financial impact of listing the new bortezomib 2.5 mg injections. The submission estimated that 35% of patients who are currently using the 3 mg injections would use the 2.5 mg injections instead. 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 pricing of bortezomib is linear therefore the derived price of bortezomib 2.5 mg injections is consistent with the other strengths of bortezomib.
- 5.3 The submission stated that the cost of bortezomib Juno to the PBS/RPBS is expected to be \$12,116,470 over six years (Year 1 \$9,491,603 to Year 6 \$12,116,470). The financial estimates model presented in the submission was inaccurate because the estimates were based on an assumption that the maximum quantity of 3 mg would decrease to 2.5 mg when bortezomib 2.5 mg is listed. The proposed listing is not expected to result in any net financial changes to the PBS. Based on the proposed price and the utilisation estimate, the listing of bortezomib 2.5 mg is expected to be cost neutral to the Commonwealth.

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 of 2.5 mg of bortezomib as a Section 100 Efficient Funding of Chemotherapy program benefit under the existing 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 1 mg, was appropriate.
- 6.3 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 existing bortezomib market. The PBAC noted that the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* governs EFC medicines, and that Section 33(2) allows substitution of brands under the same item code.
- 6.4 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.
- 6.5 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:

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