5.23 BORTEZOMIB, Solution for Injection 2.5 mg, Solution for Injection 3.5 mg, Bortezomib Ever Pharma®, Interpharma Pty Ltd

1 Purpose of Submission

1.1 The Committee Secretariat submission requested a Section 100 Efficient Funding of Chemotherapy (EFC) Program listing of two new forms of bortezomib (Bortezomib Ever Pharma®) 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection under the same circumstances as the currently listed brands of bortezomib.

2 Background

2.1 EFC medicines are governed by the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011* and subsection 33(2) allows substitution between different brands of the same chemotherapy drug.

2.2 The Product Information (PI) states that Bortezomib Ever Pharma can be administered via both intravenous (IV) and subcutaneous (SC) administration.

Registration status

2.3 Bortezomib Ever Pharma was Therapeutic Goods Administration (TGA) approved on 10 September 2021 for the same indications as the currently PBS-listed bortezomib brands.

Previous PBAC consideration

2.4 Bortezomib Ever Pharma 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection have not been previously considered by the Pharmaceutical Benefits Advisory Committee (PBAC).

2.5 At its July 2021 meeting, the PBAC recommended the listing of a new vial size of 2.5 mg bortezomib powder for injection under the same circumstances as the PBS-listed bortezomib powder for injection 1 mg, 3 mg and 3.5 mg. The 2.5 mg powder for injection was listed on the Pharmaceutical Benefits Scheme (PBS) on 1 November 2021 and was not accounted for in this submission.

3 Requested listing

3.1 The submission requested the following new listing.

Add new medicinal product pack as follows:

<table>
<tr><th>MEDICINAL PRODUCT
Form</th><th>PBS item code</th><th>Max.
Amount</th><th>№.of
Rpts</th><th>Manufacturer</th></tr>
<tr><td>BORTEZOMIB
Injection</td><td></td><td>3000 mcg</td><td>15</td><td></td></tr>
<tr><td colspan="4">Available brands</td><td></td></tr>
<tr><td>Bortezomib Ever Pharma (bortezomib 2.5 mg/mL injection, 1 mL vial)</td><td rowspan="2">NEW (Public)
NEW (Private)</td><td rowspan="2">3000 mcg</td><td rowspan="2">15</td><td rowspan="2">InterPharma</td></tr>
<tr><td>Bortezomib Ever Pharma (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)</td></tr>
<tr><td>Bortezomib Juno
(bortezomib 1.0 mg injection, 1 vial)</td><td rowspan="8">12227M (Public)
12219D (Private)</td><td rowspan="8">3000 mcg</td><td rowspan="8">15</td><td rowspan="4">Juno Pharmaceuticals Pty Ltd</td></tr>
<tr><td>Bortezomib Juno
(bortezomib 2.5 mg injection, 1 vial)</td></tr>
<tr><td>Bortezomib Juno
(bortezomib 3.5 mg injection, 1 vial)</td></tr>
<tr><td></td></tr>
<tr><td>Velcade
(bortezomib 1 mg injection, 1 vial)</td><td rowspan="4">Janssen-Cilag Pty Ltd</td></tr>
<tr><td>Velcade
(bortezomib 3 mg injection, 1 vial)</td></tr>
<tr><td>Velcade
(bortezomib 3.5 mg injection, 1 vial)</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Restriction Summary / Treatment of Concept:</td></tr>
<tr><td rowspan="3"></td><td colspan="4">Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals</td></tr>
<tr><td colspan="4">Prescriber type: ☒Medical Practitioners</td></tr>
<tr><td colspan="4">Restriction type: ☒Restricted benefit</td></tr>
<tr><td></td><td colspan="4">Indication: Multiple myeloma</td></tr>
</table>

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

4 Comparator

4.1 The submission nominated bortezomib 1 mg, 3 mg and 3.5 mg powder for injection as the main comparator. The 2.5 mg bortezomib powder for injection would also be an appropriate comparator.

4.2 The TGA considered Bortezomib Ever Pharma 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection to be bioequivalent to one of the PBS-listed brands of bortezomib powders for injection (Velcade®).

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

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from individuals (9), via the Consumer Comments facility on the PBS website. The comments described a range of benefits of treatment with bortezomib including increased life expectancy and the ability to return to work and caring responsibilities. Many commented that injection site pain is a common side effect. Some individuals mentioned that treatments such as bortezomib give sufferers of multiple myeloma hope, and that the advantages far outweigh the disadvantages.

Clinical trials

5.3 As a Committee Secretariat submission, no clinical trials were presented in the submission.

Estimated PBS utilisation and financial implications

5.4 The submission used a market-share approach to estimate there would be nil financial impact of the requested listing. The submission stated that the proposed listing was not expected to impact the overall market size for bortezomib.

5.5 The sponsor made the following assumptions about substitution in the original submission:

- The submission estimated that 35% of patients who are currently using the 3 mg powder for injection would switch to the 2.5 mg/mL solution for injection. No evidence was provided to support this assumption.
- The submission estimated that 33% of patients currently using the 3.5 mg powder for injection would switch to the 3.5 mg/1.4 mL solution for injection. No evidence was provided to support this assumption.

- The submission did not anticipate that the requested listing would replace any use of the 1 mg strength of bortezomib powder for injection.
- The sponsor did not account for the displacement of patients who are currently using the 2.5 mg powder for injection.

5.6 The requested approved ex-manufacturer price (AEMP) 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/mL and 3.5 mg/1.4 mL solutions for injection is consistent with the other strengths of bortezomib. The submission stated that, given the proportional proposed price and utilisation estimate, the requested listing will not result in a net cost to the PBS.

5.7 In the Pre-PBAC response the sponsor provided updated utilisation estimates, accounting for the patients switching from the 2.5 mg powder for injection to the 2.5 mg/mL solution for injection. A sensitivity analysis was used with 33% switching as the base case and 15% and 45% as the alternatives.

5.8 The Pre-PBAC response confirmed that when patients switching from the 2.5 mg powder for injection were incorporated the requested listing remained cost-neutral.

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

6 PBAC Outcome

6.1 The PBAC recommended the Section 100 Efficient Funding of Chemotherapy (EFC) Program listing of two new forms of bortezomib (Bortezomib Ever Pharma®) 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection under the same circumstances as the currently listed brands of bortezomib.

6.2 The PBAC noted that the derived price of bortezomib 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection was consistent with the other strengths of bortezomib.

6.3 The PBAC considered the estimates for PBS utilisation and financial impact were reasonable and noted that the proposed listing is expected to have nil cost to Government.

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(1) allows the supplier of the chemotherapy pharmaceutical benefit to use the same chemotherapy drug but a different form to make the infusion, meaning the two new forms of bortezomib (Bortezomib Ever Pharma®) 2.5 mg/mL and 3.5 mg/1.4 mL solutions for injection may be substituted for the existing forms.

6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because bortezomib solutions for injection are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed forms 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 advised that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

7 Recommended listing

7.1 Add two new medicinal product packs as follows:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts	Manufacturer
BORTEZOMIB Injection		3000 mcg	15	
Available brands				
Bortezomib Juno (bortezomib 1.0 mg injection, 1 vial)	12227M (Public) 12219D (Private)	3000 mcg	15	Juno Pharmaceuticals Pty Ltd
Bortezomib Juno (bortezomib 2.5 mg injection, 1 vial)				
Bortezomib Juno (bortezomib 3.5 mg injection, 1 vial)				
Velcade (bortezomib 1 mg injection, 1 vial)				Janssen-Cilag Pty Ltd
Velcade (bortezomib 3 mg injection, 1 vial)				
Velcade (bortezomib 3.5 mg injection, 1 vial)				
				InterPharma
Bortezomib Ever Pharma (bortezomib 2.5 mg/mL injection, 1 mL vial)				
Bortezomib Ever Pharma (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)				

Restriction Summary / Treatment of Concept:	
	Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒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.