

**5.19 BEVACIZUMAB,
Solution for I.V. infusion, 100 mg in 4 mL and 400
mg in 16 mL,
Abevmy[®],
Alphapharm Pty Ltd**

1 Purpose of Submission

- 1.1 The Category 3 submission sought a Section 100 Efficient Funding of Chemotherapy (EFC) listing of a new biosimilar brand bevacizumab (Abevmy[®]) under the same circumstances as the PBS-listed bevacizumab biosimilar Mvasi[®].

2 Background

Registration status

- 2.1 Abevmy was TGA registered on 9 September 2021 and was determined to be highly similar to the reference brand of bevacizumab, Avastin. Abevmy has the same indications as Avastin and Mvasi.

Previous PBAC consideration

- 2.2 Abevmy has not previously been considered by the PBAC.
- 2.3 Zirabev[®], another bevacizumab biosimilar, was recommended by the PBAC at its July 2020 meeting.

Current status

- 2.4 Mvasi is the only brand of bevacizumab currently listed on the PBS as an unrestricted listing. The originator brand Avastin was delisted at the request of its sponsor, Roche Products Pty Ltd, at the same time the biosimilar brand Mvasi was listed on 1 June 2021 as an unrestricted listing.

3 Requested listing

- 3.1 The submission requested listing Abevmy under the same circumstances as the existing unrestricted listings of Mvasi. The PBAC considered it would be appropriate for Abevmy to be an unrestricted listing identical to the listing of Mvasi.
- 3.2 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.

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

4 Comparator

- 4.1 The submission nominated Avastin and Mvasi as the main comparators as these represented the medicines that will likely be replaced by the PBS listing of Abevmy. This was appropriate noting that PBAC recommended listing Mvasi on a cost-minimisation basis to Avastin in November 2020.

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 that no consumer comments were received for this item.

Clinical trials

- 5.3 The submission presented the following clinical trials to support the claim of biosimilarity of Abevmy to the reference brand Avastin. As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Table 1: Trials and associated reports presented in the submission

Trial ID/First Author	Protocol/Publication title
MYL-1402O-1002	A Phase 1, double-blind, single-dose, three-treatment, parallel group, pharmacokinetic comparability study of Abevmy (Bevacizumab) manufactured for Viatris compared to US-Avastin and EU-Avastin in healthy adult male volunteers
MYL-1402O-3001	A Phase 3, multicentre, double-blind, randomized, parallel-group study to assess the efficacy and safety of Abevmy (Bevacizumab) compared with Avastin, in the first-line treatment of patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer.
BM100-CC-03-I-01	A double blind, randomized, active controlled, parallel design, comparative PK, efficacy, safety and immunogenicity study of Bevacizumab and Avastin, both in combination with XELOX (oxaliplatin and capecitabine) chemotherapy in patients with metastatic colorectal cancer.

Source: Compiled based on information in submission (pp12-13)

- 5.4 The clinical trials presented in the submission formed part of the TGA submission to extrapolate Avastin’s indication to Abevmy. The TGA considered the results of the studies demonstrated that Abevmy is highly similar to Avastin (TGA Delegate’s Overview, p15).

Economic analysis

- 5.5 The submission did not present an economic analysis as it was a Category 3 submission. The submission proposed listing Abevmy on a cost-minimisation basis to bevacizumab on the PBS.
- 5.6 Equi-effective doses were not presented in the submission.

Estimated PBS utilisation and financial implications

- 5.7 The submission considered listing Abevmy on the PBS is not expected to increase the overall use of bevacizumab on the PBS. This is appropriate as it is expected that Abevmy would substitute for Mvasi.

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) listing of bevacizumab (Abevmy®) in the form of solution for I.V. infusion 100 mg in 4 mL and solution for I.V infusion 400 mg in 16 mL, as an additional biosimilar brand under the same conditions as Mvasi®. The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Abevmy would be acceptable if it were cost-minimised to Mvasi.
- 6.2 The PBAC recommended listing Abevmy on a cost-minimisation basis to the Mvasi brand of bevacizumab and noted that this would result in no net cost to the Government because the listing of Abevmy is not expected to grow the market.
- 6.3 The PBAC noted the TGA considered the results of the clinical studies demonstrated that Abevmy is highly similar to Avastin (TGA Delegate's Overview, p15).
- 6.4 The PBAC considered the equi-effective doses of Abevmy and Mvasi to be: 100 mg of Abevmy = 100 mg of Mvasi and 400 mg of Abevmy = 400 mg of Mvasi.
- 6.5 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. Therefore, the Mvasi and Abevmy brands of bevacizumab should be treated as equivalent to each other.
- 6.6 The PBAC requested the Drug Utilisation Sub Committee (DUSC) to review the utilisation of bevacizumab after 12 months of unrestricted listing.
- 6.7 The PBAC noted Abevmy is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over Mvasi, 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.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new medicinal product pack (MPP)/trade product pack (TPP) to the existing listing for bevacizumab: 12479T and 12508H

Name and form of drug	Proprietary Name, Manufacturer
BEVACIZUMAB bevacizumab solution for I.V. infusion 100 mg in 4 mL bevacizumab solution for I.V infusion 400 mg in 16 mL	Abevmy Alphapharm Pty Ltd

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.