

5.12 BEVACIZUMAB

**Solution for I.V. infusion,
100 mg in 4 mL and 400 mg in 16 mL
Mvasi[®],
Amgen Australia Pty Ltd**

1 Purpose of Application

- 1.1 The minor submission requested a Section 100 (Efficient Funding of Chemotherapy) Authority Required (STREAMLINED) listing for a new biosimilar brand of bevacizumab (Mvasi[®]), hereafter referred to as Mvasi.

2 Background

Registration status

- 2.1 Mvasi was TGA approved on 30 June 2020 and was determined to be a biosimilar to the reference brand Avastin[®] (hereafter referred to as Avastin).
- 2.2 Mvasi was TGA approved for the same indications as the reference brand Avastin. The TGA considered the extrapolation of indications for Mvasi to all the indications of Avastin in Australia appropriate (TGA Delegate's Overview).

Previous PBAC consideration

- 2.3 Mvasi has not previously been considered by the PBAC.
- 2.4 At the time of the meeting, Avastin was the only brand of bevacizumab currently listed on the PBS. A bevacizumab biosimilar, Zirabev[®], was recommended by the PBAC at its July 2020 meeting.

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Requested listing

- 3.1 The submission requested the same listings for all indications for which the reference brand Avastin is currently PBS listed. The proposed dosage, form, strength, maximum quantity and number of repeats for Mvasi were the same as for Avastin:
- Metastatic colorectal cancer
 - Stage IV (metastatic) non-small cell lung cancer (NSCLC)
 - Relapsed or recurrent glioblastoma
 - Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

- Advanced carcinoma of cervix
- 3.2 The submission requested Authority Required (STREAMLINED) listings for all indications for Mvasi to encourage biosimilar uptake. This is the same restriction type as Avastin for all indications except for relapsed or recurrent glioblastoma, which is currently a written (delayed assessment) authority for initial treatment and telephone/online (immediate) authority for continuing treatment. The pre-PBAC response noted that lower Authority levels for biosimilars listed under the Efficient Funding of Chemotherapy (EFC) program are currently not possible and therefore accepted that for the glioblastoma indication the same the Authority level for the biosimilar and reference product is required.

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

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

Consumer comments

- 4.2 The PBAC noted and welcomed the input from an organisation (1) via the Consumer Comments facility on the PBS website. The PBAC noted the advice received from Lung Foundation Australia clarifying the likely use of Mvasi in patients with Stage IV (metastatic) non-small cell lung cancer (NSCLC). The PBAC specifically noted the advice that subsidising the use of biosimilars, in this case Mvasi, would provide clinicians and patients with additional choice of therapy to help improve quality of life for patients, reduce costs to health systems and services and patients and offer greater supply certainty. The PBAC noted that this advice was supportive of the evidence provided in the submission.
- 4.3 The minor submission presented the following clinical trials to support the claim of biosimilarity of Mvasi to the reference brand Avastin. As a minor submission, no evaluation of the clinical evidence was undertaken.

Table 1: Trials and associated reports presented in the submission

| Trial ID/First Author | Protocol title/ Publication title | Publication citation |
|-------------------------------|--|--|
| MAPLE (Study 20120265) | Efficacy and Safety of the Biosimilar ABP 215 Compared with Bevacizumab in Patients with Advanced Non squamous Non Small Cell Lung Cancer (MAPLE): A Randomized, Double-blind, Phase III Study | Thatcher N, Goldschmidt J, Thomas M et al, Clin Cancer Res 2019; 25(7) (1) |
| Study 216 (Study 20110216) | A Randomized, Single-Blind, Single-Dose, 3-Arm, Parallel Group Study to Determine the Pharmacokinetics of ABP 215 and Bevacizumab (Avastin®) in Healthy Male Subjects | Markus R, Chow V, Pan Z et al. Cancer Chemother Pharmacol 2017; 80:755–763 (2) |
| Study 174 (Study 20120174) | A randomized, single-blind, single-dose study to assess the pharmacokinetic equivalence of the biosimilar ABP 215 and bevacizumab in healthy Japanese male subjects | Hanes V, Chow N, Pan Z et al. Cancer Chemother Pharmacol 2018 82: 5; 899 – 905 (3) |

Source: Table 2.1-1 of minor submission (pp14-15)

4.4 The clinical trials presented in the submission formed part of the TGA submission to extrapolate Avastin’s indications to Mvasi. The TGA considered the results of the pharmacokinetic study, the randomised trial phase 3 clinical comparability study in the advanced NSCLC population (MAPLE) and the submitted safety data supported biosimilarity between Mvasi and Avastin (TGA Delegate’s Overview, p23).

Clinical claim

4.5 The submission claimed that Mvasi is non-inferior in terms of effectiveness, safety and immunogenicity compared to Avastin. The PBAC considered this appropriate.

Economic analysis

4.6 The minor submission proposed listing on the basis of cost-minimisation of Mvasi compared with Avastin. The equi-effective doses were estimated to be identical based on product information documents for both Mvasi and Avastin. Therefore, the equi-effective doses of Mvasi and Avastin are: 100 mg of Mvasi = 100 mg of Avastin and 400 mg of Mvasi = 400 mg of Avastin.

Table 2. Requested price for Mvasi (bevacizumab)

| Mvasi | Presentation | AEMP (published) | Estimated AEMP (25% SPR) |
|-------|-----------------|------------------|--------------------------|
| | 100 mg vial x 1 | \$303.94 | \$227.96 |
| | 400 mg vial x 1 | \$1215.75 | \$911.81 |

Source: Minor Submission, table 3.1-1 page 31; SPR= statutory price reduction

Estimated PBS usage & financial implications

4.7 The minor submission estimated there to be no financial implications to the PBS/changes in PBS usage as the submission expected Mvasi to substitute for Avastin and both drugs have the same price. Additionally, the submission noted that the listing of biosimilar bevacizumab on the PBS at lower than the current price of Avastin, due to the application of the first new brand statutory price reduction of 25%, will deliver savings to the Commonwealth.

- 4.8 As a minor submission, the financial estimates have not been independently evaluated.

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of the biosimilar brand of bevacizumab, Mvasi, under Section 100 (Efficient Funding of Chemotherapy) for all of the indications for which the reference brand, Avastin, is currently PBS-listed.
- 5.2 The PBAC recommended listing Mvasi on a cost-minimisation basis to the Avastin brand of bevacizumab, and noted that this would result in no net cost to the Government because the listing of Mvasi is not expected to grow the market.
- 5.3 The PBAC advised the equi-effective doses of Mvasi and Avastin are: 100 mg of Mvasi = 100 mg of Avastin and 400 mg of Mvasi = 400 mg of Avastin.
- 5.4 The PBAC noted that the TGA determined Mvasi to be a biosimilar to the reference brand Avastin based on the clinical evidence presented in the submission and that the extrapolation of indications for Mvasi to all the indications of Avastin registered in Australia was appropriate.
- 5.5 The PBAC noted that the biosimilar uptake driver of applying a different authority type to the biosimilar brand is not currently in place for EFC medicines. The PBAC recommended that the Authority Required (STREAMLINED) listing for all indications, except for relapsed or recurrent glioblastoma, was appropriate. The PBAC recommended the current authority type for the relapsed or recurrent glioblastoma indication should apply for Mvasi, which is a written (delayed assessment) authority for initial treatment and telephone/online (immediate) authority for continuing treatment.
- 5.6 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, Avastin and Zirabev brands of bevacizumab should be treated as equivalent to each other.
- 5.7 The PBAC noted that bevacizumab is not included on the list of PBS-listed drugs suitable for prescribing by nurse practitioners.
- 5.8 The PBAC noted that the Early Supply Rule does not currently apply to Section 100 (Efficient Funding of Chemotherapy) listings.
- 5.9 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Mvasi is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Avastin, 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.

5.10 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Add new medicinal product pack (MPP)/trade product pack (TPP) to the existing listings for bevacizumab: 11727F 11731K 11791N 11811P 10120P 10114H 7243F 10885X 11749J 11745E 10121Q, 10115J, 10881Q, 11803F, 11809M, 4400N

| MEDICINAL PRODUCT medicinal product pack | Proprietary Name, Manufacturer |
|---|---------------------------------------|
| BEVACIZUMAB bevacizumab 100 mg/4 mL injection, 4 mL vial bevacizumab 400 mg/16 mL injection, 16 mL vial | Mvasi, Amgen Australia Pty Ltd |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|--|--|-------------|-------------|
| BEVACIZUMAB Injection | 11727F (Private Hospital) 11749J (Public Hospital) | 1800 mg | 3 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 9181 / Treatment of Concept: 9166 (add the new biosimilar brand Mvasi to this restriction summary; remove 7608; no other changes) | | | |
| | 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"/> Authority Required – non-immediate/delayed assessment by Services Australia (In-writing only via mail/postal service or electronic upload to Hobart) | | |
| | Administrative Advice: Special Pricing Arrangements apply. | | |
| | Indication: Relapsed or recurrent glioblastoma | | |
| | Treatment Phase: Initial treatment | | |

| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|---|---|-------------|-------------|
| BEVACIZUMAB Injection | 11731K (Private Hospital) 11745E (Public Hospital) | 1800 mg | 5 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Restriction Summary 9103 / ToC: 9149 (delete this restriction that is now more than 12 months old) | | | |
| | Treatment Phase: Grandfather treatment | | |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | №.of Rpts |
|---|---|-------------|-----------|
| BEVACIZUMAB Injection | 11731K (Private Hospital) 11745E (Public Hospital) | 1800 mg | 5 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Restriction Summary 9137 / Treatment of Concept 9102 (as at 1 November 2020; no change other than to update Department of Human Services to Services Australia) | | | |
| 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"/> Authority Required – immediate/real-time assessment by Services Australia (online/telephone) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Indication: Relapsed or recurrent glioblastoma | | | |
| Treatment Phase: Continuing treatment | | | |
| Clinical criteria: | | | |
| Patient must have previously received PBS-subsidised treatment with this drug for this condition | | | |
| AND | | | |
| Clinical criteria: | | | |
| Patient must not have developed further symptomatic progression while being treated with this drug for this condition | | | |
| AND | | | |
| Clinical criteria: | | | |
| The treatment must not exceed a dose of 10 mg per kg every 2 weeks; or | | | |
| The treatment must not exceed a dose of 15 mg per kg every 3 weeks | | | |
| Prescribing Instructions: | | | |
| Symptomatic progression is defined as: | | | |
| i) Deterioration of neurologic function which may include motor dysfunction, seizures, lack of co-ordination, changes to personality, reduced ability to communicate, neurocognitive decline; OR | | | |
| ii) Increasing symptoms of raised intracranial pressure which may include headache, nausea, vomiting or poorly controlled vasogenic oedema. | | | |
| Administrative Advice: | | | |
| Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | |
| Administrative Advice: | | | |
| Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). | | | |

Current Authority Required (Streamline) listings to which the new biosimilar brand Mvasi can be added to:

| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|--|---|-------------|-------------|
| BEVACIZUMAB Injection | 10120P (Private Hospital) 10115J (Public Hospital) | 900 mg | 5 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 4814: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| 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"/> Authority Required – Streamlined (4814) | | | |
| Indication: Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer | | | |
| Treatment Phase: Initial treatment | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |

| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|--|---|-------------|-------------|
| BEVACIZUMAB Injection | 10114H (Private Hospital) 10121Q (Public Hospital) | 900 mg | 11 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 4584: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| 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"/> Authority Required – Streamlined (4584) | | | |
| Indication: Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer | | | |
| Treatment Phase: Continuing treatment | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|---|--|-------------|-------------|
| BEVACIZUMAB Injection | 10885X (Private Hospital) 10881Q (Public Hospital) | 1800 mg | 7 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 6337: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| | 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"/> Authority Required – Streamlined (6337) | | |
| | Indication: Advanced carcinoma of cervix | | |
| | Treatment Phase: Initial treatment | | |
| | Administrative Advice: Special Pricing Arrangements apply. | | |
| Abbreviated Restriction Summary 6353: (attach the new Mvasi brand to this restriction summary; remove 7608; no other changes) | | | |
| | Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (6353) | | |
| | Administrative Advice: Special Pricing Arrangements apply. | | |
| | Indication: Advanced carcinoma of cervix | | |
| | Treatment Phase: Continuing treatment | | |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | №.of Rpts |
|---|---|-------------|-----------|
| BEVACIZUMAB Injection | 11791N (Private Hospital) 11809M (Public Hospital) | 1800 mg | 5 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 9346: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| 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"/> Authority Required – Streamlined (9346) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC) | | | |
| Treatment Phase: Initial treatment 1 | | | |
| Abbreviated Restriction Summary 9347: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (9347) | | | |
| Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Treatment Phase: Initial treatment 2 | | | |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|---|---|-------------|-------------|
| BEVACIZUMAB Injection | 11811P (Private Hospital) 11803F (Public Hospital) | 1800 mg | 7 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 9566: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| 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"/> Authority Required – Streamlined (9566) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC) | | | |
| Treatment Phase: Continuing treatment | | | |
| Restriction Summary 9454: (delete this Grandfather listing that will be 12 months old on 1 October 2020) | | | |
| Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (9454) | | | |
| Indication: Stage IV (metastatic) non-small cell lung cancer (NSCLC) | | | |
| Treatment Phase: Grandfather treatment | | | |

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| MEDICINAL PRODUCT Form | PBS item code | Max. Amount | No. of Rpts |
|--|---|-------------|-------------|
| BEVACIZUMAB Injection | 7243F (Private Hospital) 4400N (Public Hospital) | 900 mg | 11 |
| Available brands | | | |
| Avastin (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Avastin (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Mvasi (bevacizumab 400 mg/16 mL injection, 16 mL vial) | | | |
| Mvasi (bevacizumab 100 mg/4 mL injection, 4 mL vial) | | | |
| Abbreviated Restriction Summary 9060 / ToC 4594: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| 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"/> Authority Required – Streamlined (4594) | | | |
| Indication: Metastatic colorectal cancer | | | |
| Treatment Phase: Initial treatment | | | |
| Clinical criteria | | | |
| The condition must be previously untreated | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Abbreviated Restriction Summary 9150 / ToC 4587: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (4587) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Indication: Metastatic colorectal cancer | | | |
| Treatment Phase: Continuing treatment | | | |
| Abbreviated Restriction Summary 9165 / ToC 4939: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (4939) | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Indication: Metastatic colorectal cancer | | | |
| Treatment Phase: Initial treatment | | | |
| Clinical criteria | | | |
| Patient must have RAS wild-type metastatic colorectal cancer | | | |
| Administrative Advice: This drug is not PBS-subsidised for use in combination with an anti-EGFR antibody. | | | |
| Abbreviated Restriction Summary 9104 / ToC 4968: (attach the new Mvasi biosimilar brand to this restriction summary; remove 7608; no other changes) | | | |
| Restriction Type: <input checked="" type="checkbox"/> Authority Required – Streamlined (4968) | | | |
| Indication: Metastatic colorectal cancer | | | |
| Administrative Advice: Special Pricing Arrangements apply. | | | |
| Treatment Phase: Continuing treatment | | | |

6.2 Delete grandfather restriction from items 11731K, 11745E, 11811P, and 11803F as listings will be 12 months old on 1 October 2020.

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

7 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.

8 Sponsor's Comment

The sponsor had no comment.