

**5.23 FARICIMAB,
Solution for intravitreal injection 21 mg in 0.175 mL
(120 mg per mL) pre-filled syringe,
Vabysmo[®],
ROCHE PRODUCTS PTY LTD**

1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule Authority Required (Written/online PBS authorities systems) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of a new form of faricimab (Vabysmo[®]), intravitreal injection 0.175 mL pre-filled syringe (PFS) containing 21 mg of faricimab at a concentration of 120 mg per mL, for the treatment of macular oedema secondary to retinal vein occlusion (RVO).
- 1.2 Listing was requested on a cost-minimisation (CMA) basis to the currently listed form of faricimab, intravitreal injection 0.24 mL vial containing 28.8 mg of faricimab at a concentration of 120 mg per mL.

2 Background

- 2.1 Faricimab 28.8 mg in 0.24 mL intravitreal injection vial is currently listed on the PBS as a General Schedule Authority Required (Written/online PBS authorities systems) listing for the initial treatment and an Authority Required (STREAMLINED) listing for the continuing treatment of diabetic macular oedema (DMO), neovascular age-related macular degeneration (nAMD), and RVO.

Registration status

- 2.2 The PFS form of faricimab (21 mg in 0.175 mL) was registered in the Australian Register of Therapeutic Goods (ARTG) for the treatment of nAMD, DMO and RVO on 30 September 2024. The submission requested the listing of the new PFS form (21 mg in 0.175 mL) for the RVO indication only. A separate application to list this PFS form for the currently listed indications (nAMD and DMO) was received by the Department to implement the May 2022 PBAC recommendation (see paragraphs 2.4 and 2.5).
- 2.3 The recommended dose in the TGA Product Information (PI) for RVO is 6 mg of faricimab administered by intravitreal injection every 4 weeks for three or more consecutive treatments. Thereafter, treatment may be individualised using a treat-and-extend approach. Each vial or PFS provides a usable amount to deliver a single dose of 0.05 mL solution containing 6 mg of faricimab for the treatment of a single eye.

Previous PBAC consideration

- 2.4 At its May 2022 meeting, the PBAC recommended the listing of faricimab in the forms of 28.8 mg in 0.24 mL intravitreal injection vial and 24.0 mg in 0.2 mL intravitreal injection PFS for the treatment of DMO and nAMD. These listings were based on a cost-minimisation to PBS-listed anti-vascular endothelial growth factor (anti-VEGF) treatments, such as aflibercept and ranibizumab, on a 1:1 injection basis (paragraph 7.1, DMO and nAMD Public Summary Documents (PSD), May 2022 PBAC meeting).
- 2.5 The submission noted that the PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953* (the Act), that faricimab 28.8 mg in 0.24 mL vial and faricimab 24.0 mg in 0.2 mL PFS should be considered equivalent for the purposes of substitution (i.e., ‘a’ flagged in the Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purposes of substitution) (paragraph 7.12, DMO PSD, May 2022 PBAC meeting, paragraph 7.13, nAMD PSD, May 2022 PBAC meeting). Faricimab 24.0 mg in 0.2 mL PFS has not been listed for any indication at the time of PBAC consideration.
- 2.6 At its July 2024 meeting, the PBAC recommended listing the vial form of faricimab for the treatment of RVO on a cost-minimisation basis to the lowest cost PBS-listed anti-VEGF treatment (paragraph 7.1, RVO PSD, July 2024 PBAC meeting).
- 2.7 The submission noted that the PFS form was not included in the TGA application to extend the use of faricimab for the treatment of patients with RVO at the time of the PBAC submission in July 2024. As such, the July 2024 submission requested both forms be listed for this indication, but the PBAC recommended only the vial form of faricimab.

3 Requested listing

- 3.1 The submission requested that the new PFS form of faricimab be listed under the same conditions as the current PBS listings for the vial form of faricimab for the RVO indication.

Add new medicinal product pack as follows:

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No.of Rpts | Available brands |
|---|---|----------------------|-------------------|---------------|----------------------|
| FARICIMAB | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | NEW | 1 | 1 | 2 | ^a Vabysmo |
| Restriction Summary [new1] / Treatment of Concept: [new1A] | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload) | | | | |

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| Prescribing rule level | Administrative Advice: Special Pricing Arrangements apply. |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. |
| | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. |
| | Administrative Advice: Pharmaceutical benefits that have the form faricimab 0.24 mL injection vial and pharmaceutical benefits that have the form faricimab 0.175 mL injection syringe are equivalent for the purposes of substitution. |
| | Indication: Branch retinal vein occlusion with macular oedema |
| | Treatment Phase: Initial treatment |
| | Treatment criteria: |
| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist |
| | Clinical criteria: |
| | Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO). |
| | AND |
| | Clinical criteria: |
| | Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment |
| | AND |
| | Clinical criteria: |
| | The condition must be diagnosed by optical coherence tomography; OR |
| | The condition must be diagnosed by fluorescein angiography |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |
| | Prescribing Instructions: Authority approval for initial treatment of each eye must be sought. |
| | Prescribing Instructions: The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records. |

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| | <p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at servicesaustralia.gov.au</p> <p>Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)</p> <p>Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos</p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> |
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| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No.of Rpts | Available brands |
|---|---|----------------------|-------------------|---------------|----------------------|
| FARICIMAB | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | NEW | 1 | 1 | 2 | ^a Vabysmo |
| Restriction Summary [new2] / Treatment of Concept: [new2A] | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload) | | | | |
| Prescribing rule level | Administrative Advice: Special Pricing Arrangements apply. | | | | |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. | | | | |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. | | | | |
| | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. | | | | |
| | Administrative Advice: Pharmaceutical benefits that have the form faricimab 0.24 mL injection vial and pharmaceutical benefits that have the form faricimab 0.175 mL injection syringe are equivalent for the purposes of substitution. | | | | |
| Indication: Central retinal vein occlusion with macular oedema | | | | | |
| Treatment Phase: Initial treatment | | | | | |
| Treatment criteria: | | | | | |
| Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist | | | | | |
| Clinical criteria: | | | | | |

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| | Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO) |
| | AND |
| | Clinical criteria: |
| | Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment |
| | AND |
| | Clinical criteria: |
| | The condition must be diagnosed by optical coherence tomography; OR |
| | The condition must be diagnosed by fluorescein angiography |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |
| | Prescribing Instructions: The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records. |
| | Prescribing Instructions: Authority approval for initial treatment of each eye must be sought. |
| CAR | Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at servicesaustralia.gov.au Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001 |

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| MEDICINAL PRODUCT medicinal product pack | | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|---|---|---------------------|----------------------|-------------------|--------------|----------------------|
| FARICIMAB | | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | | NEW | 1 | 1 | 2 | ^a Vabysmo |
| Restriction Summary [new3]/ Treatment of Concept [new3A]: | | | | | | |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) | | | | | |
| Prescribing rule level | Administrative Advice: Special Pricing Arrangements apply. | | | | | |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. | | | | | |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. | | | | | |
| | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. | | | | | |
| | Administrative Advice: Pharmaceutical benefits that have the form faricimab 0.24 mL injection vial and pharmaceutical benefits that have the form faricimab 0.175 mL injection syringe are equivalent for the purposes of substitution. | | | | | |
| Indication: Branch retinal vein occlusion with macular oedema | | | | | | |
| Treatment Phase: Continuing treatment | | | | | | |
| Treatment criteria: | | | | | | |
| Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist | | | | | | |
| Clinical criteria: | | | | | | |
| Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye | | | | | | |
| AND | | | | | | |
| Clinical criteria: | | | | | | |
| The treatment must be the sole PBS-subsidised therapy for this condition | | | | | | |
| Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). | | | | | | |

| MEDICINAL PRODUCT medicinal product pack | | PBS item code | Max. qty packs | Max. qty units | №.of Rpts | Available brands |
|--|--|---------------------|----------------------|-------------------|--------------|----------------------|
| FARICIMAB | | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | | NEW | 1 | 1 | 2 | ^a Vabysmo |
| Restriction Summary [new4]/ Treatment of Concept [new4A]: | | | | | | |
| Category / Program: GENERAL – General Schedule (Code GE) | | | | | | |

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| Concept ID (for internal Dept. use) | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) |
| Prescribing rule level | Administrative Advice: Special Pricing Arrangements apply. |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. |
| | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. |
| | Administrative Advice: Pharmaceutical benefits that have the form faricimab 0.24 mL injection vial and pharmaceutical benefits that have the form faricimab 0.175 mL injection syringe are equivalent for the purposes of substitution. |
| | Indication: Central retinal vein occlusion with macular oedema |
| | Treatment Phase: Continuing treatment |
| | Treatment criteria: |
| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist |
| | Clinical criteria: |
| | Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |
| | Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). |

- 3.2 The submission requested that the PFS form be marked as equivalent to the vial form for RVO in the Schedule, with a NOTE stating: ‘Pharmaceutical benefits that have the form faricimab 0.24 mL injection vial and pharmaceutical benefits that have the form faricimab 0.175 mL injection syringe are equivalent for the purposes of substitution.’

4 Comparator

- 4.1 The submission did not nominate a comparator but indicated that the PFS form will substitute for the vial form in the same population, if recommended for listing.
- 4.2 Aflibercept (2 mg/0.05 mL vial, 2 mg/0.05 mL PFS) and ranibizumab (2.3 mg/0.23 mL vial and 1.65 mg/0.165 mL PFS) are other anti-VEGF therapies currently listed for RVO. The PBAC previously recommended listing the IV form of faricimab on a cost-minimisation basis with aflibercept and accepted the proposed dose equivalence of faricimab 6 mg injection and aflibercept 2 mg injection, consistent with a 1:1 dose relativity (paragraph 7.2, faricimab PSD, July 2024 PBAC meeting).

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 did not provide any clinical evidence comparing the PFS form to the vial form for RVO and stated that no additional clinical data from what was previously considered by the PBAC for RVO in July 2024 is available. The submission claimed that the PFS form delivers the same 6 mg dose of faricimab as the vial form but provides clinicians with a more convenient treatment option as it is ready to use and does not require reconstitution.

Economic analysis

5.4 The submission requested that the published dispensed price for maximum quantity (DPMQ) and published ex-manufacturer price (AEMP) of the PFS form be the same as for the currently PBS-listed vial form, noting the effective AEMP of the vial form for the RVO indication was under negotiation at the time of submission lodgement, but was expected to be consistent with the agreed effective price per injection of the vial presentation in RVO.

Estimated PBS usage and financial implications

5.5 The submission did not provide the estimated usage and financial implications for listing the PFS form of faricimab. However, the submission estimated no net financial impact to the PBS/RPBS, assuming the effective AEMP for the PFS form is the same as for the vial form, and the PFS form will substitute for the vial form on a 1:1 dose equivalence for RVO in clinical practice.

5.6 As a Category 4 submission, the financial estimates have not been independently evaluated.

Quality use of medicines

5.7 Should the two forms of faricimab be considered equivalent at the pharmacy level (i.e., 'a'-flagged in the Schedule), patients may be provided a different form than initially instructed when prescribed or on subsequent repeats. Appropriate education and training should be provided to clinicians administering different forms of faricimab as instructions for use, handling, and shelf life of faricimab for intravitreal injection are different for each form in the TGA-approved PI.

6 PBAC Outcome

- 6.1 The PBAC recommended listing faricimab 21 mg in 0.175 mL (120 mg per mL) pre-filled syringe (PFS) intravitreal injection under the same circumstances as the current PBS listings for faricimab 28.8 mg in 0.24 mL (120 mg per mL) vial for the treatment of macular oedema secondary to retinal vein occlusion (RVO). The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of faricimab PFS would be acceptable if it were cost-minimised to the lowest cost PBS-listed anti-vascular endothelial growth factor (VEGF) treatment for the same indication.
- 6.2 The PBAC advised that the new PFS form of faricimab should be cost-minimised to the lowest cost alternative anti-VEGF therapy listed on the PBS for RVO (i.e., faricimab vial, aflibercept and ranibizumab), based on a 1:1 dose relativity for RVO, consistent with its May 2022 and July 2024 recommendations (paragraph 7.1, DMO and nAMD PSD, May 2022 PBAC meeting; paragraph 7.1, RVO PSD, July 2024 PBAC meeting).
- 6.3 The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953*, that faricimab 28.8 mg in 0.24 mL vial and faricimab 21 mg in 0.175 mL PFS should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule). The PBAC considered the inclusion of the Administrative Advice stating: 'Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe are equivalent for the purposes of substitution' in the restrictions to be appropriate.
- 6.4 The PBAC considered that listing the new PFS form of faricimab would not result in any additional cost to the PBS/RPBS, as the PFS form is expected to substitute for the vial form at a 1:1 dose equivalence.
- 6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because faricimab 21 mg in 0.175 mL PFS is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed anti-VEGF therapies, 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 2022* for Pricing Pathway A were not met.
- 6.6 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 item:

| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|--|---|-------------------|-------------------|----------------|----------------------|
| FARICIMAB | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | NEW | 1 | 1 | 2 | ^a Vabysmo |
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) | | | | |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners | | | | |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (written/online PBS authorities system) | | | | |
| Prescribing rule level | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. | | | | |
| | Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001 | | | | |
| | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. | | | | |
| | Administrative Advice: Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe are equivalent for the purposes of substitution. | | | | |
| | Administrative Advice: No increase in the maximum number of repeats may be authorised. | | | | |
| | Administrative Advice: Special Pricing Arrangements apply. | | | | |
| Restriction Summary 16335 / Treatment of Concept: 16319 | | | | | |
| | Indication: Branch retinal vein occlusion with macular oedema | | | | |
| | Treatment Phase: Initial treatment | | | | |
| | Treatment criteria: | | | | |
| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist | | | | |
| | Clinical criteria: | | | | |
| | Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO) | | | | |
| | AND | | | | |
| | Clinical criteria: | | | | |
| | Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 20 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/400), in the eye proposed for treatment | | | | |
| | AND | | | | |

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| | Clinical criteria: |
| | The condition must be diagnosed by optical coherence tomography; or |
| | The condition must be diagnosed by fluorescein angiography |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |
| | AND |
| | Prescribing Instructions: Authority approval for initial treatment of each eye must be sought. |
| | Prescribing Instructions: The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records. |
| Restriction Summary 16342 / Treatment of Concept: 16309 | |
| | Indication: Central retinal vein occlusion with macular oedema |
| | Treatment Phase: Initial treatment |
| | Treatment criteria: |
| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist |
| | Clinical criteria: |
| | Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO) |
| | AND |
| | Clinical criteria: |
| | Patient must have documented visual impairment defined as a best corrected visual acuity score between 73 and 24 letters based on the early treatment diabetic retinopathy study chart administered at a distance of 4 metres (approximate Snellen equivalent 20/40 to 20/320), in the eye proposed for treatment |
| | AND |
| | Clinical criteria: |
| | The condition must be diagnosed by optical coherence tomography; or |
| | The condition must be diagnosed by fluorescein angiography |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |
| | Prescribing Instructions: Authority approval for initial treatment of each eye must be sought. |

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| | <p>Prescribing Instructions: The first authority application for each eye must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include: (1) Details (date, unique identifying number/code or provider number) of the optical coherence tomography or fluorescein angiogram report. If the application is submitted through HPOS form upload or mail, it must include: (a) details of the proposed prescription; and (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice). All reports must be documented in the patient's medical records.</p> |
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| MEDICINAL PRODUCT medicinal product pack | PBS item code | Max. qty packs | Max. qty units | No. of Rpts | Available brands |
|---|------------------|-------------------|-------------------|----------------|----------------------|
| FARICIMAB | | | | | |
| faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe | NEW | 1 | 1 | 2 | ^a Vabysmo |

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|---|---|
| Concept ID (for internal Dept. use) | Category / Program: GENERAL – General Schedule (Code GE) |
| | Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners |
| | Restriction type: <input checked="" type="checkbox"/> Authority Required (STREAMLINED) |

| | | |
|------------------------|--|--|
| Prescribing rule level | | Administrative Advice: Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application. |
| | | Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). |
| | | Administrative Advice: No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. |
| | | Administrative Advice: Pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial and pharmaceutical benefits that have the form faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL syringe are equivalent for the purposes of substitution. |
| | | Administrative Advice: No increase in the maximum number of repeats may be authorised. |
| | | Administrative Advice: Special Pricing Arrangements apply. |

Restriction Summary 16310 / Treatment of Concept: 13387

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| | Indication: Branch retinal vein occlusion with macular oedema |
| | Treatment Phase: Continuing treatment |
| | Treatment criteria: |
| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist |
| | Clinical criteria: |
| | Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |

Restriction Summary 16293 / Treatment of Concept: 13336

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| | Indication: Central retinal vein occlusion with macular oedema |
| | Treatment Phase: Continuing treatment |
| | Treatment criteria: |

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| | Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist |
| | Clinical criteria: |
| | Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye |
| | AND |
| | Clinical criteria: |
| | The treatment must be the sole PBS-subsidised therapy for this condition |

These restrictions 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.