

## 6.02 FARICIMAB

### Solution for intravitreal injection 28.8 mg in 0.24 mL (120 mg/mL), Vabysmo<sup>®</sup>, Roche Products Pty Limited.

#### 1 Purpose of submission

- 1.1 The Category 2 submission requested a General Schedule, Authority Required listing for faricimab for the treatment of macular oedema secondary to retinal vein occlusion (RVO).
- 1.2 Listing was requested on the basis of a cost-minimisation approach (CMA) versus aflibercept in the proposed target population. The key components of the clinical issues addressed in the submission are summarised in Table 1.

**Table 1: Key components of the clinical issue addressed by the submission (as stated in the submission)**

Component	Description
Population	Patients with retinal vein occlusion
Intervention	Faricimab
Comparator	Aflibercept 2 mg
Outcomes	Primary efficacy outcome: best corrected visual acuity Secondary / other efficacy outcomes: change in central subfield thickness, macular leakage, quality of life Adverse events (ocular and non-ocular)
Clinical claim	In patients with RVO, faricimab is non-inferior, in terms of efficacy and safety, to aflibercept

Source: Table 1.1, p2 of the submission.

#### 2 Background

##### **Registration status**

- 2.1 The submission was made under the Therapeutic Goods Administration (TGA)/ Pharmaceutical Benefits Advisory Committee (PBAC) parallel process for “macular oedema secondary to RVO”. At the time of the PBAC meeting, the TGA Delegate’s Overview was available. The Delegate requested advice from the Advisory Committee on Medicines (ACM) regarding (i) inclusion of anti-vascular endothelial growth factor (anti-VEGF) treatment-experienced patients in the indication; and (ii) any other issues the ACM deemed relevant. The Delegate stated there was no reason, at this time, that the application should not be approved for registration for RVO.

##### **Previous consideration**

- 2.2 This is the first consideration of faricimab by the PBAC for RVO. Faricimab is currently listed on the PBS for the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular oedema (DMO).

### 3 Requested listing

MEDICINAL PRODUCT Form	Dispensed Price for Max. Qty	Max. qty packs	Max. qty units	№.of Rpts	Available brands
<b>Initiation</b>					
Faricimab solution for intravitreal injection 28.8 mg / 0.24 mL injection, 0.24 mL vial <sup>a</sup>	\$933.61 (published price)	1	1	2	Vabysmo
<b>Continuation</b>					
Faricimab solution for intravitreal injection 28.8 mg / 0.24 mL injection, 0.24 mL vial <sup>a</sup>	\$933.61 (published price)	1	1	2	Vabysmo
Category / Program: General Schedule					
Prescriber type	Medical Practitioners				
Condition:	Branch retinal vein occlusion with macular oedema Central retinal vein occlusion with macular oedema				
<b>Treatment phase:</b>	<b>Initial treatment</b>				
Restriction:	Authority Required – Immediate / Real time assessment by Services Australia (telephone / online application avenues)				
Treatment criteria:	Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist.				
Clinical criteria: Branch retinal vein occlusion with macular oedema	Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO), AND 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 The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography, AND The treatment must be the sole PBS-subsidised therapy for this condition.				
Clinical criteria: Central retinal vein occlusion with macular oedema	Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO), AND 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 20/400), in the eye proposed for treatment, AND The condition must be diagnosed by optical coherence tomography; OR The condition must be diagnosed by fluorescein angiography, AND The treatment must be the sole PBS-subsidised therapy for this condition.				
Administrative advice	<u>Note:</u> Special Pricing Arrangements apply. <u>Note:</u> No increase in the maximum number of repeats may be authorised. <u>Note:</u> No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. <u>Note:</u> Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.				
Administrative advice	Authority approval for initial treatment of each eye must be sought. 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) A completed authority prescription form; 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.				
<b>Treatment phase:</b>	<b>Continuing treatment</b>				

Restriction:	Authority Required - Streamlined
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 The treatment must be the sole PBS-subsidised therapy for this condition.
Administrative advice	<u>Note:</u> Special Pricing Arrangements apply. <u>Note:</u> No increase in the maximum number of repeats may be authorised. <u>Note:</u> No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye. <u>Note:</u> Where both eyes are affected by the condition, a quantity of 2 units can be requested on the same authority prescription form.
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)

Source: Table 1.6, p29 of the submission.

TBC = to be confirmed

<sup>a</sup> Each vial of 0.24 mL contains 28.8 mg of faricimab at a concentration of 120 mg/mL. This provides a usable amount to deliver a single dose of 0.05 mL solution containing 6 mg of faricimab.

- 3.1 The submission proposed a special pricing arrangement (SPA) with the effective price to be informed by the CMA.
- 3.2 The proposed faricimab restrictions for RVO were consistent with the current PBS restrictions for aflibercept and ranibizumab for central retinal vein occlusion (CRVO) and branch retinal vein occlusion (BRVO) but broader than the inclusion criteria in the pivotal trials, BALATON and COMINO, which included only treatment-naïve patients.
- 3.3 The submission did not propose a separate restriction for hemicentral retinal vein occlusion (HRVO). The COMINO trial included both HRVO and CRVO patients. The ESC considered that it would be appropriate for HRVO patients to access faricimab through the CRVO restriction.
- 3.4 The submission requested PBS listing for a vial (faricimab 28.8 mg in 0.24 mL) and a pre-filled syringe (faricimab 24.0 mg in 0.2 mL); however, the pre-filled syringe presentation is not part of the TGA application to extend the indication to RVO (vial presentation only). The Pre-Sub-Committee Response (PSCR) stated that an additional application to the TGA for the pre-filled syringe was submitted in May 2024. The ESC and the PBAC acknowledged the sponsor's request to consider this presentation at the July 2024 meeting, but noted that there is a requirement for lodgement of a registration dossier with the TGA prior to making a submission to the PBAC.
- 3.5 The submission requested grandfathering provisions, however, did not provide an estimate of the number of patients eligible for grandfathering.

*For more detail on PBAC's view, see section 7 PBAC outcome.*

## 4 Population and disease

- 4.1 RVO is caused by the obstruction of retinal veins that drain blood from the back of the eye, which can be caused by a thrombus, external compression, or vessel wall disease. RVO leads to increased pressure within the retinal veins, causing haemorrhages,

macular oedema, ischemia, and neovascularisation. RVO is classified based on the site of retinal occlusion. BRVO refers to obstruction of a branch retinal vein, CRVO is occlusion of the entire central retinal vein. HRVO is included in the submission as a sub-type of CRVO and involves occlusion of the superior or inferior branches of the central retinal vein. In Australia, the prevalence of RVO is estimated to be 0.96%, with BRVO observed in 0.72% of the population and CRVO in 0.24% of the population<sup>1</sup>. The American Academy of Ophthalmology stated the incidence of HRVO is rare compared to BRVO and CRVO.

- 4.2 In the acute phase of RVO, chronic macular oedema, primarily due to VEGF-mediated breakdown of the blood-retinal barrier and increased venous pressure proximal to the occlusion site, is a major driver of vision loss. The prognosis depends on the degree of nonperfusion and occlusion location, as greater ischemia portends worse vision outcomes, making macular oedema a primary therapeutic target to prevent vision loss in RVO.
- 4.3 Faricimab is a humanised bispecific immunoglobulin G1 (IgG1) antibody that acts through inhibition of two distinct pathways by neutralisation of both angiopoietin-2 (Ang-2) and VEGF-A reducing vascular permeability and inflammation while restoring stability.

## 5 Comparator

- 5.1 The submission nominated aflibercept as the main comparator. The main arguments provided in support of this nomination were that:
- Aflibercept is the most commonly used anti-VEGF injection for RVO on the PBS, with a near 80% market share, and thus is the therapy most likely to be replaced in clinical practice.
  - Ranibizumab is another anti-VEGF therapy PBS listed for RVO, however its utilisation has been declining year-on-year since 2021.
- 5.2 The ESC and the PBAC agreed with the evaluation that the nominated comparator, aflibercept, was appropriate given it is the therapy that prescribers would most likely replace if faricimab is listed.
- 5.3 In the context of the cost-minimisation approach taken by the submission, a further consideration for the PBAC is that, under Section 101(3B) of the *National Health Act 1953*, when the proposed medicine is substantially more costly than an alternative therapy, the Committee cannot make a positive recommendation unless it is satisfied that, for some patients, the proposed medicine provides a significant improvement in

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<sup>1</sup> Keel S, Xie J, Foreman J, van Wijngaarden P, Taylor HR, Dirani M. Prevalence of retinal vein occlusion in the Australian National Eye Health Survey. *Clin Exp Ophthalmol*. 2018 Apr;46(3):260-265. doi: 10.1111/ceo.13031. Epub 2017 Aug 25. PMID: 28752913.

efficacy and/or reduction of toxicity over the alternative therapy. If the Committee is so satisfied, it must make a statement to this effect.

- 5.4 For the requested population, ranibizumab may be considered an alternative therapy (in addition to aflibercept) because it could be replaced in practice. The ESC and the PBAC noted the submission did not provide any evidence that faricimab provides a significant improvement in efficacy or reduction of toxicity over the alternative therapies. The PBAC previously accepted non-inferiority between aflibercept and ranibizumab on the basis of 1:1 dose relativity (paragraph 7.12, aflibercept CRVO Public Summary Document (PSD), November 2014 PBAC meeting, paragraph 7.8, aflibercept BRVO PSD, November 2015 PBAC meeting).

*For more detail on PBAC's view, see section 7 PBAC outcome.*

## **6 Consideration of the evidence**

### ***Sponsor hearing***

- 6.1 There was no hearing for this item.

### ***Consumer comments***

- 6.2 The PBAC noted and welcomed the input from the Macular Disease Foundation Australia via the Consumer Comments facility on the PBS website clarifying the likely use of faricimab in clinical practice. The PBAC specifically noted the advice that patients and clinicians are anticipating alternative effective anti-VEGF agents for treating RVO that may deliver longer intervals between eye injections, with efficacy and safety outcomes that are comparable with other current PBS-listed therapies for RVO.

### ***Clinical trials***

- 6.3 The submission was based on 2 head-to-head trials: BALATON (n= 553) in patients with BRVO and COMINO (n= 729) in patients with CRVO or HRVO, comparing faricimab to aflibercept.
- 6.4 Details of the trials presented in the submission are provided in Table 2.

**Table 2: Trials and associated reports presented in the submission.**

Trial ID	Protocol title/ Publication title	Publication citation
BALATON (GR41984)	Primary CSR Study GR41984 (BALATON). A phase III, multicentre, randomised, double-masked, active comparator-controlled study to evaluate the efficacy and safety of faricimab in patients with macular oedema secondary to branch retinal vein occlusion.	February 2023
	Update CSR Study GR41984 (BALATON): A phase III, multicentre, randomised, double-masked, active comparator-controlled study to evaluate the efficacy and safety of faricimab in patients with macular oedema secondary to branch retinal vein occlusion.	October 2023
	A Study to Evaluate the Efficacy and Safety of Faricimab in Patients with Macular Edema Secondary to Branch Retinal Vein Occlusion Hoffmann-La Roche, Chugai Pharmaceutical. A study to evaluate the efficacy and safety of faricimab in participants with macular oedema secondary to branch retinal vein occlusion.	ICTRP WHO Euctr P.L. 2020 Clinicaltrials.gov Date not provided
COMINO (GR41986)	Primary CSR Study GR41986 (COMINO). A phase III, multicentre, randomised, double-masked, active comparator-controlled study to evaluate the efficacy and safety of faricimab in patients with macular oedema secondary to central of hemiretinal vein occlusion.	February 2023.
	ICTRP WHO Euctr D.E. A study to evaluate the efficacy and safety of faricimab in patients with macular oedema secondary to central retinal or hemiretinal vein occlusion	ICTRP WHO Euctr P.L Date not provided
	A study to evaluate the efficacy and safety of faricimab in participants With macular oedema secondary to central retinal or hemiretinal vein occlusion. Hoffmann-La Roche, Chugai Pharmaceutical. A study to evaluate the efficacy and safety of faricimab in participants with macular oedema secondary to central retinal or hemiretinal vein occlusion.	ICTRP WHO Euctr P.L Date not provided Clinicaltrials.gov Date not provided

Source: Table 2.3, p43 of the submission.

CSR = clinical study report; ICTRP = International Clinical Trials Registry Platform; VEGF = vascular endothelial growth factor; WHO = World Health Organization.

### 6.5 The key features of the direct randomised trials are summarised in Table 3.

**Table 3: Key features of the included evidence**

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes
<b>Faricimab vs aflibercept</b>					
BALATON	553	R, DB, MC 72 weeks	Low	BRVO	Primary: Change in BCVA at 24 weeks Key secondary: Proportion of patients with absence of macular oedema. NEI-VFQ-25 score.
COMINO	729	R, DB, MC 72 weeks	Low	C/HRVO	

Source: Table 2.4, p47, Table 2.12, p60 and Table 2.5, p53 of the submission.

BCVA = best corrected visual acuity; BRVO = branch retinal vein occlusion; C/HRVO = central or hemi-central retinal vein occlusion; DB = double blind; MC = multi-centre; NEI-VFQ-25 = National Eye Institute Visual Function Questionnaire 25; R= randomised.

6.6 The BALATON and COMINO trials comprised 2 parts. In Part 1 patients were randomised to receive either faricimab or aflibercept every 4 weeks (Q4W) for 24 weeks. Part 2 was a non-comparative phase (from Week 24 to Week 68 with an end of study visit at Week 72), during which patients in both the faricimab Q4W and aflibercept Q4W arms were treated with a flexible dosing interval regimen of faricimab based on disease personalised treatment intervals (PTI). Therefore, comparative data for faricimab versus aflibercept were only available up to 24 weeks.

- 6.7 The BALATON and COMINO trials recruited men and women aged 18 years or older, with macular oedema due to BRVO (BALATON) or C/HRVO (COMINO) and excluded patients with prior treatment for macular oedema due to RVO. Under the proposed restrictions, both treatment-experienced and treatment-naïve patients would be eligible for treatment with faricimab in Australia. Patients who have previously received treatment may present a refractory form of the disease less amenable to modification by sequential therapies. Therefore, the results of BALATON and COMINO conducted in treatment-naïve patients may not be generalisable to the targeted Australian population. The impact on comparative effectiveness and safety is unknown.
- 6.8 The BALATON and COMINO trial design used a fixed Q4W dosing regimen for 24 weeks, requiring a total of 6 injections for both faricimab and aflibercept. This is not consistent with the approved Product Information (PI) for aflibercept, which recommends a loading phase of Q4W dosing for 12 weeks (3 injections) followed by a treat and extend (T&E) regimen after Week 12. The proposed faricimab PI is ambiguous regarding the number of initiating doses, stating that 3 or more consecutive monthly injections may be needed initially before transitioning to a T&E approach. Considering the difference in the trial protocols and the approved/proposed dosing schedules for aflibercept/faricimab, the number of injections for both faricimab and for aflibercept during the first 24 weeks of follow-up may have been overestimated in the trials, potentially also resulting in an overestimate for adverse reactions related to injection frequency compared to what will be expected in clinical practice. However, the trial design is unlikely to have introduced differential bias favouring one therapy over the other, as the differences between the approved/proposed PIs and the trial protocols apply to both faricimab and aflibercept.
- 6.9 The primary outcome in the BALATON and COMINO trials was change from baseline in best corrected visual acuity (BCVA) measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) letter score at Week 24 using a non-inferiority margin of 4 letters. A non-inferiority margin of 4 letters has previously been accepted by the PBAC for the treatment of patients with subfoveal choroidal neovascularisation (paragraph 6.11, brolocizumab PSD, November 2019 PBAC meeting and paragraph 7.5, faricimab nAMD PSD, May 2022 PBAC meeting). Additionally, BCVA is a clinically relevant outcome that has previously been accepted by the PBAC in patients with RVO (aflibercept PSD, November 2014 PBAC meeting; aflibercept PSD, November 2015 PBAC meeting; and ranibizumab PSD, July 2014 PBAC meeting).

### ***Comparative effectiveness***

- 6.10 The results of the primary outcome of change from baseline in BCVA at Week 24 for the BALATON and COMINO trials are summarised in Table 4. In the intention to treat (ITT) populations, the lower confidence limits of the mean treatment differences between the arms at Week 24 (-2.2 and -2.5 letters, respectively) were greater than

(within) -4 letters, thereby meeting the pre-specified non-inferiority margin of 4 letters. Overall, mean increases in visual acuity were observed in all treatment arms at Week 24.

**Table 4: Change from baseline in BCVA in the study eye at Week 24 in the BALATON and COMINO trials (MMRM method, ITT population)**

Trial ID	Faricimab		Aflibercept		Mean difference (95% CI)
	Mean BCVA at baseline (SE) (BALATON N=276 COMINO N=366)	Mean BCVA change at Week 24 (95% CI)	Mean BCVA at baseline (SE) (BALATON N=277 COMINO N=363)	Mean BCVA change at Week 24 (95% CI)	
BALATON	57.5 (0.78)	16.9 (15.7, 18.1)	57.6 (0.73)	17.5 (16.3, 18.6)	-0.6 (-2.2, 1.1)
COMINO	50.2 (0.85)	16.9 (15.4, 18.3)	50.7 (0.86)	17.3 (15.9, 18.8)	-0.4 (-2.5, 1.6)

Source: Table 2,13 p63 of the submission. Table 10, p70 of the COMINO Primary CSR, Table 10, p67 of the BALATON Primary CSR, p176 of the BALATON Primary CSR and p181 of the COMINO Primary CSR.

BCVA = best corrected visual acuity; CI = confidence interval; ITT = intention to treat; MMRM = mixed-effect model with repeated measures; N = sample size; NR = not reported; SE = standard error.

For the MMRM analysis, the model was adjusted for treatment group, visit, visit by treatment group interaction, baseline BCVA (continuous), baseline BCVA score ( $\leq 54$  letters vs  $\geq 55$  letters), and region (United States and Canada, Asia, and the rest of the world). An unstructured covariance structure was used. Observed BCVA assessments were used regardless of the occurrence of intercurrent events. Missing data were implicitly imputed by MMRM. Invalid BCVA values were excluded from analysis. 95% CI is a rounding of 95.03% CI.

6.11 Table 5 details the difference in BCVA between baseline and the average of Weeks 64, 68 and 72. The difference in BCVA from baseline was comparable between arms and similar to the difference observed at Week 24. In BALATON and COMINO, the BCVA gains achieved at Week 24 were maintained through Week 72, during which time all patients were on the faricimab PTI dosing regimen.

**Table 5: Results of change from baseline in BCVA in the study eye at Week 64/68/72 in BALATON and COMINO trials: MMRM method, ITT population**

Trial ID	Faricimab Q4W to faricimab PTI		Aflibercept Q4W to faricimab PTI	
	Mean BCVA at baseline (SE) (BALATON N=276; COMINO N=366)	Mean BCVA change (95% CI)	Mean BCVA at baseline (SE) (BALATON N=277; COMINO N=363)	Mean BCVA change (95% CI)
BALATON	57.5 (0.78)	18.1 (16.9, 19.4)	57.7 (0.73)	18.8 (17.5, 20.0)
COMINO	50.2 (0.85)	16.9 (15.2, 18.6)	50.7 (0.86)	17.1 (15.4, 18.8)

Source: Table 2.14, p66 of the submission, Table 9, p85 of the COMINO Updated CSR, Table 9, p84 of the BALATON Updated CSR, p211 of the COMINO Updated CSR and p204 of the BALATON Updated CSR.

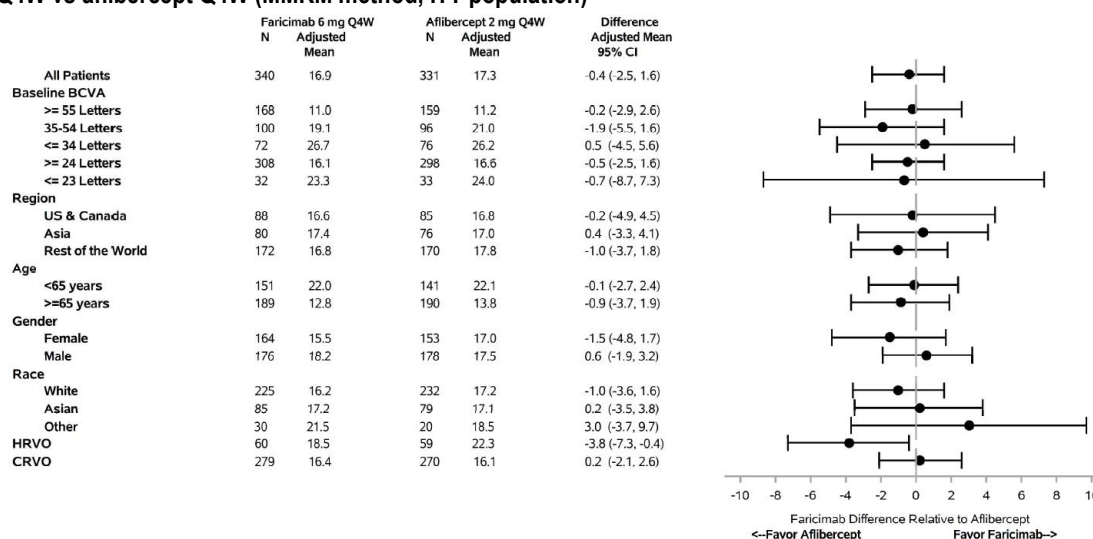
BCVA = best corrected visual acuity; CI = confidence interval; ITT = intention to treat; MMRM = missed model for repeated measures; N = sample size; NR = not reported; PTI = personalised treatment interval; Q4W=every four weeks; SE = standard error.

Change from baseline in BCVA is the average over Weeks 64, 68, 72.

6.12 In the BALATON and COMINO trials, there were no differences between the faricimab and aflibercept arms in subgroup analyses of the adjusted mean change from baseline in BCVA at Week 24 for each subgroup: baseline BCVA, region, age, gender and race. However, in the HRVO subgroup of the COMINO trial, the mean change from baseline in BCVA was statistically significantly higher (better) in the aflibercept arm at Week 24 compared to the faricimab arm (Figure 1), noting that the mean difference in BCVA (-3.8 letters) is not considered clinically significant. The proportion of HRVO patients at baseline was similar across arms with 62/366 (17.0%) and 65/363 (18.1%) patients

in the faricimab and aflibercept arms, respectively. The HRVO subgroup was not prospectively defined as a randomisation stratification factor in the COMINO trial design and the HRVO subgroup size was small. Based on anatomical and physiological characteristics, the ESC and the PBAC considered that it was unlikely that patients with HRVO responded differently to faricimab than to other anti-VEGF therapy.

Figure 1. COMINO: Subgroup forest plot of change from baseline in BCVA in the study eye at Week 24 for faricimab Q4W vs aflibercept Q4W (MMRM method, ITT population)



Source: Figure 2.4, p65 of the submission.

BCVA = best corrected visual acuity; CI = confidence interval; CRVO = central retinal vein occlusion; HRVO = hemi-central retinal vein occlusion; ITT = intention to treat; MMRM = mixed-model repeated-measure; Q4W = every four weeks; US = United States.

For the MMRM analysis, the model adjusted for treatment group, visit, visit-by-treatment group interaction, baseline BCVA (continuous), baseline BCVA ( $\leq 34$  letters, 35–54 letters and  $\geq 55$  letters) and region (US and Canada, Asia and the rest of the world). The stratification factor is excluded if it is the subgroup. An unstructured covariance structure is used. Missing data were implicitly imputed by MMRM. Invalid BCVA values were excluded from analysis. The bars represent 95.03% CI.

### Comparative harms

6.13 The incidence of adverse events was comparable between treatment arms in the BALATON and COMINO trials. No significant treatment differences in the safety profile were observed among treatment arms in the trials (Table 6). There was 1 death reported in the COMINO trial which was considered not related to the study treatment. There were no events of retinal vasculitis, or occlusive retinal vasculitis in the study eye reported in the BALATON or COMINO trials at Week 24.

**Table 6: Summary of adverse events in the BALATON and COMINO trials through Week 24 (SAF)**

	BALATON		COMINO		Pooled	
	Faricimab Q4W n/N (%)	Aflibercept Q4W n/N (%)	Faricimab Q4W n/N (%)	Aflibercept Q4W n/N (%)	Faricimab Q4W n/N (%)	Aflibercept Q4W n/N (%)
Any AE	125/276 (45.3)	128/274 (46.7)	174/365 (47.7)	200/361 (55.4)	299/641 (46.6)	328/635 (51.7)
Any SAE	12/276 (4.3)	17/274 (6.2)	32/365 (8.8)	33/361 (9.1)	44/641 (6.9)	50/635 (7.9)
Any AESI	1/276 (0.4)	2/274 (0.7)	9/365 (2.5)	14/361 (3.9)	10/641 (1.6)	16/635 (2.5)
Total number of patients withdrawn from study treatment due to an AE	1/276 (0.4)	1/274 (0.4)	3/365 (0.8)	3/361 (0.8)	4/641 (0.6)	4/635 (0.6)
<b>Ocular events, study eye</b>						
AE	45/276 (16.3)	56/274 (20.4)	84/365 (23.0)	100/361 (27.7)	129/641 (20.1)	156/635 (24.6)
SAE	3/276 (1.1)	2/274 (0.7)	9/365 (2.5)	12/361 (3.3)	12/641 (1.9)	14/635 (2.2)
AE leading to withdrawal from study treatment	0	0	3/365 (0.8)	2/361 (0.6)	3/641 (0.5)	2/635 (0.3)
Treatment-related AEs	1/276 (0.4)	2/274 (0.7)	14/365 (3.8)	8/361 (2.2)	15/641 (2.3)	10/635 (1.6)
Treatment-related SAEs	0	0	3/365 (0.8)	2/361 (0.6)	3/641 (0.5)	2/635 (0.3)
<b>AESI</b>	<b>1/276 (0.4)</b>	<b>2/274 (0.7)</b>	<b>8/365 (2.2)</b>	<b>12/361 (3.3)</b>	<b>9/641 (1.4)</b>	<b>14/635 (2.2)</b>
VA score drop $\geq 30$ <sup>a</sup>	1/276 (0.4)	2/274 (0.7)	6/365 (1.6)	6/361 (1.7)	7/641 (1.1)	8/635 (1.3)
Associated with severe IOI	0	0	0	0	0	0
Intervention required to prevent permanent vision loss <sup>b</sup>	0	0	2/365 (0.5)	6/361 (1.7)	2/641 (0.3)	6/635 (0.9)
<b>Adjudicated APTC events</b>	<b>3/276 (1.1)</b>	<b>4/274 (1.5)</b>	<b>4/365 (1.1)</b>	<b>5/361 (1.4)</b>	<b>7/641 (1.1)</b>	<b>9/635 (1.4)</b>
Non-fatal MI	1/276 (0.4)	2/274 (0.7)	1/365 (0.3)	2/361 (0.6)	2/641 (0.3)	4/635 (0.6)
Non-fatal stroke	2/276 (0.7)	2/274 (0.7)	3/365 (0.8)	2/361 (0.6)	5/641 (0.8)	4/635 (0.6)
Death	0	0	0	1/361 (0.3)	0	1/635 (0.2)

Source: Table 2.27, p93, Table 2.30, p107 of the submission.

AE = adverse event; AESI = adverse event of special interest; APTC = Antiplatelet Trialists' Collaboration; IOI = intraocular inflammation; MI = myocardial infarction; Q4W = every four weeks; SAE = serious adverse event; SAF = safety analysis set; VA = visual acuity.

<sup>a</sup> Drop in VA score  $\geq 30$  VA score lasting more than one hour.

<sup>b</sup> Intervention required to prevent permanent vision loss is defined as required surgical or medical intervention to prevent permanent loss of sight. Multiple occurrences of the same AE in one individual are counted only once.

### **Benefits/harms**

- 6.14 A benefits and harms table was not presented as the submission made a claim of non-inferiority.

### **Clinical claim**

- 6.15 The submission described faricimab as non-inferior in terms of effectiveness and safety compared with aflibercept. While the evaluation and ESC considered that this claim may be adequately supported by the evidence presented in the submission, they noted the lack of comparative data beyond Week 24 in the T&E maintenance phase.
- 6.16 Notwithstanding the uncertainty around the lack of comparative data beyond Week 24, the evaluation noted that BCVA gains achieved at Week 24 were maintained through Week 72 in both the BALATON and COMINO trials during the period where all patients received faricimab using a T&E approach.
- 6.17 Under the proposed restrictions, both treatment-experienced and treatment-naïve patients would be eligible for treatment with faricimab, in contrast to the BALATON and COMINO trials which were conducted in treatment-naïve patients only (paragraph 6.7). The results of the BALATON and COMINO trials conducted in treatment-naïve patients may not be generalisable to the targeted Australian population if treatment-experienced patients are less amenable to modification by sequential therapies.
- 6.18 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was adequately demonstrated, with no particular safety signal, noting that the BALATON and COMINO trials provided direct trial evidence for faricimab versus aflibercept up to 24 weeks.

### **Economic analysis**

- 6.19 The submission presented a CMA comparing faricimab to aflibercept based on BALATON and COMINO. The presentation of a CMA was appropriate given the claim of non-inferior efficacy and safety of faricimab compared with aflibercept.
- 6.20 The submission presented the CMA over a 1-year time horizon. A 1-year time horizon has previously been accepted by the PBAC for aflibercept in BRVO and CRVO<sup>2</sup>. The CMAs in previous submissions for faricimab in DMO and nAMD were conducted over a 2-year time horizon to account for differences in costs in the first and subsequent years<sup>3</sup>.
- 6.21 The key components and assumptions of the CMA are presented in Table 7.

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<sup>2</sup> Paragraph 6.23, aflibercept BRVO PSD, Nov 2015; paragraph 6.21, aflibercept CRVO PSD, Nov 2014 PBAC meetings.

<sup>3</sup> Paragraph 6.46, faricimab DMO PSD, May 2022; paragraph 6.36, faricimab nAMD PSD, May 2022 PBAC meetings.

**Table 7: Key components and assumptions of the cost-minimisation approach**

Component	Assumption
Therapeutic claim: effectiveness	Based on evidence presented in the submission, effectiveness was assumed to be non-inferior
Therapeutic claim: safety	Based on evidence presented in the submission, safety was assumed to be non-inferior
Evidence base	Direct comparison of faricimab and aflibercept from BALATON and COMINO trials
Equi-effective doses	Faricimab Q4W is equivalent to aflibercept Q4W on a 1:1 equi-effective dose
Direct medicine costs	Equivalent; faricimab Q4W would cost the same as aflibercept Q4W per injection
Other costs or cost offsets	No

Source: Table 3.1, p140 of the submission.

Q4W = every four weeks.

- 6.22 The submission assumed a 1:1 equi-effective dose ratio between faricimab 6 mg and aflibercept 2 mg, based on equivalent dosing of faricimab and aflibercept (Q4W through to Week 24) in the BALATON and COMINO trials. The evaluation considered that the application of a 1-year time horizon based on 24-week (6 months) data, does not account for the duration of treatment intervals that would be observed in clinical practice in the T&E maintenance phase of treatment, and therefore limits an evidence-based estimate of the equi-effective doses of faricimab and aflibercept.
- 6.23 The annual number of injections estimated by the CMA was based on the mean number of injections (5.8 injections in both faricimab and aflibercept arms) reported in the trials at 24 weeks, extrapolated to a 52-week period (12.6 injections). The ESC and the evaluation considered this extrapolation was unsupported by the evidence given that no comparative data were available beyond 24 weeks in BALATON and COMINO. The number of doses (12.6 for both agents) was higher than expected using a T&E approach. The PSCR clarified that 12.6 doses over 1 year was indicative only, and that the CMA assumed there would be 1 vial per administration, with dosing based on three monthly loading doses followed by a T&E approach for both faricimab and aflibercept, based on a 1:1 equi-effective dose ratio and the approved/proposed dosing schedules for aflibercept/faricimab.
- 6.24 The submission asserted that given the faricimab mechanism of action and its demonstrated efficacy in nAMD and DMO, similar outcomes to those observed in the BALATON and COMINO trials are likely with fewer injections of faricimab, and therefore a 1:1 dose equivalence is a conservative assumption. The PBAC noted that, while a 1:1 relativity is conservative compared to the relativity recommended for faricimab vs aflibercept 2 mg for nAMD (0.55:1 over two years)<sup>4</sup> that it is not conservative compared to the relativity recommended for faricimab vs aflibercept 2 mg for DMO (1.11:1 over two years)<sup>5</sup>. The pre-PBAC response maintained that a 1:1 dose equivalence for faricimab:aflibercept in RVO is appropriate, given the claim of

<sup>4</sup> Paragraph 6.35, faricimab nAMD PSD, May 2022 PBAC meeting.

<sup>5</sup> Paragraph 6.45, faricimab DMO PSD, May 2022 PBAC meeting.

non-inferiority in the comparative period of the RCTs, and the identical dosing and regimen for faricimab and aflibercept [up to Week 24].

6.25 The results of the CMA based on the assumed effective AEMP of aflibercept using a 1:1 equi-effective dose ratio is presented in Table 8.

**Table 8: Results of the cost-minimisation approach, assumed effective AEMP**

Component	Faricimab	Aflibercept
<b>Treatment cost</b>		
Cost per administration (assumed effective AEMP)	\$	\$
Estimated frequency of administration over 1 year	12.6 <sup>a</sup>	12.6 <sup>a</sup>
Total cost per year	\$	\$

Source: constructed by the evaluation.

AEMP = approved ex-manufacturer price.

Note: the AEMP of faricimab was estimated based on an assumed effective price for aflibercept of \$.

a. Assumed 1:1 dose equivalence between faricimab and aflibercept based on the mean number of injections (5.8 injections in both faricimab and aflibercept arms) reported in the BALATON and COMINO trials at 24 weeks extrapolated to a 52-week estimate. The PSCR clarified that frequency of administration was estimated based on the trial-based extrapolation, but that the CMA assumed there would be 1 vial per administration (with dosing based on 3 monthly loading doses then T&E) for both faricimab and aflibercept based on a 1:1 equi-effective dose.

6.26 As the PBAC has accepted the clinical claim of overall non-inferior effectiveness and safety, the CMA approach must establish that the cost per patient for treatment with faricimab would be no more than the cost per patient of aflibercept or the lowest cost alternative. Where these cost per patient calculations are uncertain, the guiding principle is that the Australian Government should not bear the financial risk of this uncertainty because the Australian population already has access to therapy that is at least as effective and safe.

### ***Drug cost/patient/year***

6.27 The drug cost per patient per year is presented in Table 10 using an assumed effective ex-manufacturer price of \$ per vial.

**Table 10: Drug cost per patient per year for proposed and comparator drugs**

	Faricimab trial dose and duration	Faricimab CMA	Faricimab financial estimates	Aflibercept trial dose and duration	Aflibercept CMA	Aflibercept financial estimates
Mean dose/scripts		12.6 <sup>a</sup>			12.6 <sup>a</sup>	
DPMQ per script		\$			\$	
Cost/patient/year		\$			\$	

Source: constructed during the evaluation based on Section 3 and Section 4 of the submission.

CMA= cost-minimisation approach; DPMQ = dispensed price maximum quantity mg = milligrams.

Notes: The financial estimates presented by the submission assumed faricimab use would be the same as aflibercept

<sup>a</sup> Assumed 1:1 script equivalence between faricimab and aflibercept based on the mean number of injections (5.8 injections in both faricimab and aflibercept arms) reported in the BALATON and COMINO trials at 24 weeks extrapolated to a 52-week estimate.

### ***Estimated PBS usage & financial implications***

6.28 This submission was not considered by DUSC.

6.29 The submission used a market share approach to estimate the extent of use and financial impact of listing faricimab on the PBS. This was consistent with the claim of non-inferiority in terms of effectiveness and safety compared with aflibercept and the

CMA presented by the submission. The market size of anti-VEGF therapies for RVO was estimated from the historical use of aflibercept for RVO. The sources of data utilised are shown in Table 11.

Table 11: Key inputs for financial estimates

Data	Value applied and source	Comment
<b>Treatment utilisation</b>		
<b>Anti-VEGF market without listing of faricimab</b>		
Estimated anti-VEGF market for 2023 (scripts)	77,671 Medicare statistics. Estimated as the number of scripts for aflibercept item numbers relevant to the RVO indication (11991D, 13138L, 12132M and 13141P).	This was reasonable; however, the submission did not account for the utilisation of ranibizumab for RVO. Although the utilisation of ranibizumab has been declining, its overall market share in RVO was 20% in 2023.
Annual market growth (in scripts)	█ <sup>1</sup> in Year 1 to █ <sup>2</sup> in Year 6. The submission applied a linear trend using the method of least squares to extrapolate projected PBS utilisation in 2024 to 2029.	The % growth applied by the submission ranged from █% in the first year to █% in Year 6. The submission inappropriately applied the linear trend function to a portion of the model rather than the observed data to estimate the utilisation of aflibercept in 2024 to 2029.
Projected market size of aflibercept for RVO	From █ <sup>3</sup> scripts in Year 1 to █ <sup>3</sup> scripts in Year 6. Calculated 2023 scripts for aflibercept and the assumed annual growth of RVO market.	
<b>RVO market with the listing of faricimab</b>		
Uptake rate (rate of substitution)	█% within 4 years. Assumed uptake rates for Year 1 (█%) and Year 4 (█%) and estimated values for Year 2 to Year 4 as a constant rate of change based on the assumed values.	The submission did not provide any justification for the assumed uptake rate. The submission conducted sensitivity analyses to examine the impact of varying the uptake rate by 10%. The ESC considered that the uptake rate may be higher in patients who switch from ranibizumab to faricimab.
Script equivalence	Faricimab is a direct substitute for aflibercept on a 1:1 basis.	This was consistent with the CMA, noting that no trial data or utilisation data are available to inform script equivalence in the maintenance phase.

Source: Table 4.2 p145, Table 4.3 p145, Table 4.7, p147, Table 4.9 p148 and Section 4 Workbook.xlsx, spreadsheet 'Projected growth'. DUSC = Drug Utilisation Sub Committee PBAC = Pharmaceutical Benefit Advisory Committee; PBS = Pharmaceutical Benefit Scheme; PSD = Public Summary Document; RPBS = Repatriation Pharmaceutical Benefit Scheme; VEGF = Vascular Endothelial Growth Factor.

The redacted values correspond to the following ranges

<sup>1</sup> 20,000 to < 30,000

<sup>2</sup> 10,000 to < 20,000

<sup>3</sup> 100,000 to < 200,000

6.30 The submission predicted that the introduction of faricimab into the current RVO market will result in █% of all RVO patients receiving faricimab for PBS-subsidised anti-VEGF maintenance treatment by Year 4 of its listing. The evaluation considered that the assumed uptake rate for faricimab may be overestimated given that the clinical trial evidence presented by the submission showed similar effectiveness and safety for faricimab and aflibercept. The uptake rate of up to █% in Year 6 was consistent with the uptake rate previously applied in the faricimab submissions for DMO and nAMD, however it was lower in Year 1 of listing (█% versus █%; paragraph 6.58, faricimab DMO PSD, paragraph 6.51, faricimab nAMD PSD, May 2022 PBAC meetings). While the uptake rate for faricimab in the nAMD and DMO indications would be expected to be higher given it has a longer dosing interval relative to its

nominated comparator (aflibercept) in those indications, the ESC considered that some clinicians may similarly expect that treatment with faricimab may result in longer treatment intervals than aflibercept despite the lack of comparative data after Week 24.

6.31 The submission did not account for faricimab loading doses in the initial year of treatment for patients who may switch from aflibercept (or ranibizumab) to faricimab. If the administration frequency for patients previously receiving aflibercept was longer than 4 weeks, this would result in additional costs to Government.

6.32 The estimated utilisation and financial impact of listing faricimab on the PBS using the assumed effective prices are presented in Table 12.

**Table 12: Estimated use and financial implications (assumed effective prices)**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use of faricimab</b>						
Number of scripts dispensed	1	2	3	4	5	6
<b>Estimated financial implications of faricimab</b>						
Cost to PBS/RPBS less copayments	7	8	9	10	11	11
<b>Estimated financial implications for aflibercept</b>						
Cost to PBS/RPBS less copayments	-12	-12	-12	-12	-12	-12
<b>Net financial implications</b>						
Net cost to PBS/RPBS	13	13	13	13	13	13
Net cost to MBS	13	13	13	13	13	13
Net cost to Government	13	13	13	13	13	13

Source: Table 4.10, p149, Table 4-23, p134 of the submission Section 4 Workbook.xlsx, spreadsheet '7. Net changes – MBS'; MBS = Medicare Benefits Schedule; mg = milligram; PBS = Pharmaceutical Benefit Scheme; RPBS = Repatriation Pharmaceutical Benefit Scheme.

The redacted values correspond to the following ranges

<sup>1</sup> 20,000 to < 30,000

<sup>2</sup> 40,000 to < 50,000

<sup>3</sup> 60,000 to < 70,000

<sup>4</sup> 80,000 to < 90,000

<sup>5</sup> 90,000 to < 100,000

<sup>6</sup> 100,000 to < 200,000

<sup>7</sup> \$10 million to < \$20 million

<sup>8</sup> \$30 million to < \$40 million

<sup>9</sup> \$40 million to < \$50 million

<sup>10</sup> \$60 million to < \$70 million

<sup>11</sup> \$70 million to < \$80 million

<sup>12</sup> net cost saving

<sup>13</sup> \$0 to < \$10 million

6.33 The submission estimated a zero total net cost to the PBS/RPBS of listing faricimab. The estimated net cost of zero to the PBS/RPBS was dependent on realisation of 1:1 dose equivalence of aflibercept and faricimab in clinical practice and no occurrences of switching from other anti-VEGF therapies with a lower injection frequency (i.e. longer time between administrations).

- 6.34 The PBAC noted it had previously recommended a risk sharing arrangement with expenditure caps for aflibercept for this indication (paragraph 6.36, aflibercept PSD, November 2015 PBAC meeting).

*For more detail on PBAC's view, see section 7 PBAC outcome.*

## **7 PBAC Outcome**

- 7.1 The PBAC recommended the listing of faricimab for the treatment of macular oedema secondary to retinal vein occlusion (RVO). The PBAC's recommendation was based on, among other matters, its assessment that the cost-effectiveness of faricimab would be acceptable if it were cost-minimised to the lowest cost alternative medicine currently PBS-listed for RVO.
- 7.2 The PBAC recommended the listing of faricimab on a cost-minimisation basis with aflibercept. The PBAC accepted the proposed dose equivalence of faricimab 6 mg injection and aflibercept 2 mg injection, consistent with 1:1 dose relativity.
- 7.3 The PBAC noted that there is a residual unmet need for longer acting anti-VEGF therapies in eye diseases and acknowledged the consumer comments on this topic provided by the Macular Disease Foundation Australia.
- 7.4 The PBAC noted that the requested restriction wording, maximum quantity, repeats and treating specialists for faricimab in RVO are identical to aflibercept in branch RVO (BRVO) and central RVO (CRVO). However, the PBAC noted that the requested initial telephone/online authority for faricimab was not consistent with the aflibercept and ranibizumab PBS listings for initial treatment, which both require a written authority, and considered that a written authority would also be required for faricimab. The PBAC noted that this would align with the PBAC's advice that the initial phase listings for aflibercept and ranibizumab in RVO should remain written authorities (November 2021 PBAC meeting<sup>6</sup>). The PBAC considered that patients currently receiving non-PBS faricimab would be able to initiate faricimab via the proposed initial treatment listing, and the requested grandfathering restriction would not be necessary.
- 7.5 Under the proposed restrictions, both treatment-experienced and treatment-naïve patients would be eligible for treatment with faricimab. The PBAC considered it appropriate to allow patients to switch from PBS-listed aflibercept or ranibizumab to faricimab, particularly those who are currently having ongoing monthly injections and may benefit from a potentially longer-acting agent.
- 7.6 The PBAC considered the proposed clinical place in therapy for faricimab as an alternative treatment option to the currently listed anti-VEGF therapies for RVO was reasonable. The PBAC considered the nominated comparator of aflibercept 2 mg was

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<sup>6</sup> <https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-11/pbac-web-outcomes-11-2021-v2.pdf>

- appropriate and noted that ranibizumab was also an alternative therapy as it could be replaced in clinical practice.
- 7.7 The PBAC considered that the claim of non-inferior effectiveness of faricimab compared to aflibercept was adequately demonstrated, with no evident safety signal. The PBAC noted that the BALATON and COMINO trials only provided direct trial evidence for faricimab versus aflibercept up to 24 weeks and the BCVA gains achieved at Week 24 were maintained through Week 72 during the period where all patients received faricimab using a treat and extend (T&E) approach.
- 7.8 The PBAC noted the dosing relativity of 1:1 was based on 24-week randomised controlled trial data (from BALATON and COMINO), which does not reflect how either faricimab or aflibercept will be used in clinical practice (paragraph 6.8), and that no comparative data is available to inform the dosing relativity based on a T&E approach (paragraph 6.15). The PBAC noted there were uncertainties regarding the appropriate dose relativity but considered that, on balance, 1:1 was likely to be conservative.
- 7.9 The PBAC noted the submission did not provide any evidence that faricimab provides a significant improvement in efficacy or reduction of toxicity over the alternative anti-VEGF therapies, aflibercept and ranibizumab. The PBAC noted that it previously accepted non-inferiority between aflibercept (2 mg injection) and ranibizumab (0.5 mg injection) for RVO on the basis of 1:1 dose relativity. The PBAC considered that faricimab would be cost-effective if it were cost-minimised to the lowest cost alternative anti-VEGF treatment for RVO.
- 7.10 The PBAC accepted the market share approach to estimate the cost neutral financial impact of listing faricimab on the PBS for RVO. The PBAC considered that it would be unlikely for faricimab to require more doses than aflibercept, and unlikely for PBS listing to increase market growth in RVO. The PBAC noted that the patients who may switch from aflibercept (or ranibizumab) to faricimab would likely be on frequent (monthly) dosing, and therefore would not incur a cost to government in terms of the additional monthly loading doses involved in switching.
- 7.11 The PBAC recommended that faricimab should be included under the existing risk sharing arrangement (RSA) for anti-VEGF medicines used to treat RVO with no increase in expenditure caps.
- 7.12 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because faricimab is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over aflibercept, 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.
- 7.13 The PBAC noted that this submission is not eligible for an Independent Review, as it received a positive recommendation.

**Outcome:**

Recommended

## 8 Recommended listing

### 8.1 Add new restriction as follows:

MEDICINAL PRODUCT Medicinal product pack	PBS item code	Max. qty (packs)	Max. qty (units)	No. of repeats	Proprietary name and manufacturer
FARICIMAB faricimab 6 mg/0.05 mL intraocular injection, 0.05 mL vial	NEW (Initial treatment) NEW (Continuing treatment)	1	1	2	Vabysmo Roche Products Pty Ltd

#### Initial treatment of RVO

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required – In Writing/Online PBS Authorities Systems
	<b>Indication:</b> Branch retinal vein occlusion with macular oedema
	<b>Treatment Phase:</b> Initial treatment
	<b>Treatment criteria:</b>
	Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist
	<b>Clinical criteria:</b>
	Patient must have visual impairment due to macular oedema secondary to branched retinal vein occlusion (BRVO)
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must be diagnosed by optical coherence tomography; OR
	The condition must be diagnosed by fluorescein angiography
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Prescribing Instructions:</b> Authority approval for initial treatment of each eye must be sought
	<b>Prescribing Instructions:</b> 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).

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	All reports must be documented in the patient's medical records.
	<p><b>Administrative Advice:</b> 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 <a href="http://servicesaustralia.gov.au">servicesaustralia.gov.au</a></p> <p>Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/hpos">www.servicesaustralia.gov.au/hpos</a>)</p> <p>Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at <a href="http://www.servicesaustralia.gov.au/hpos">www.servicesaustralia.gov.au/hpos</a></p> <p>Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p><b>Administrative Advice:</b> Special Pricing Arrangements apply</p>
	<p><b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised</p>
	<p><b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.</p>
	<p><b>Administrative Advice:</b> Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application</p>

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required – In Writing/Online PBS Authorities Systems
	<b>Indication:</b> Central retinal vein occlusion with macular oedema
	<b>Treatment Phase:</b> Initial treatment
	<b>Treatment criteria:</b>
	Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist
	<b>Clinical criteria:</b>
	Patient must have visual impairment due to macular oedema secondary to central retinal vein occlusion (CRVO)
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must be diagnosed by optical coherence tomography; OR

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	The condition must be diagnosed by fluorescein angiography
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Prescribing Instructions:</b> Authority approval for initial treatment of each eye must be sought
	<p><b>Prescribing Instructions:</b>  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>
	<p><b>Administrative Advice:</b>  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 <a href="http://servicesaustralia.gov.au">servicesaustralia.gov.au</a></p> <p>Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/hpos">www.servicesaustralia.gov.au/hpos</a>)</p> <p>Alternatively, applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at <a href="http://www.servicesaustralia.gov.au/hpos">www.servicesaustralia.gov.au/hpos</a></p> <p>Or mailed to:  Services Australia  Complex Drugs  Reply Paid 9826  HOBART TAS 7001</p>
	<p><b>Administrative Advice:</b>  Special Pricing Arrangements apply</p>
	<p><b>Administrative Advice:</b>  No increase in the maximum number of repeats may be authorised</p>
	<p><b>Administrative Advice:</b>  No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye.</p>
	<p><b>Administrative Advice:</b>  Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application</p>

**Continuing treatment of RVO**

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required – STREAMLINED [new code]
	<b>Indication:</b> Branch retinal vein occlusion with macular oedema

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	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>Administrative Advice:</b> 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).
	<b>Administrative Advice:</b> Special Pricing Arrangements apply
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised for applications for treatment of one eye
	<b>Administrative Advice:</b> Where both eyes are affected by the condition, a quantity of 2 units can be requested through the same authority application

<b>Concept ID</b>	<b>Category / Program:</b> GENERAL – General Schedule (Code GE)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction Level / Method:</b> <input checked="" type="checkbox"/> Authority Required – STREAMLINED [new code]
	<b>Indication:</b> Central retinal vein occlusion with macular oedema
	<b>Treatment Phase:</b> Continuing treatment
	<b>Treatment criteria:</b>
	Must be treated by an ophthalmologist or by an accredited ophthalmology registrar in consultation with an ophthalmologist
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition for the same eye
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>Administrative Advice:</b> 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).
	<b>Administrative Advice:</b> Special Pricing Arrangements apply
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised
	<b>Administrative Advice:</b> 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

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

## **9 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.

## **10 Sponsor's Comment**

The sponsor had no comment.