Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

Date 20 February 2025
Re: Package advice lock procedure medicinal product faricimab (Vabysmo®) for visual impairment due to blockage of veins in the eye

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of faricimab (Vabysmo®) for the treatment of visual impairment due to macular oedema caused by blockage of veins in the eye. This advice was prompted by the inclusion of faricimab in the package lock procedure for expensive medicinal products.

The macula (or yellow spot) is the central part of the retina, the light-sensitive layer at the back of the eye. The macula makes you see sharply in the centre (central vision). Blockage of the main blood vessel (vein) or smaller branches that carry the blood away from the retina causes increased pressure in these blood vessels. Also, the eye receives less blood and oxygen, creating new branches of poor-quality veins. As a result, fluid leaks into the retina causing swelling of the macula (macular oedema). This causes visual impairment (visual deterioration). In the Netherlands, an estimated 116,000 people suffer from this form of visual impairment. Patients are currently treated with anti-vascular, endothelial growth factor inhibitors (anti-VEGF inhibitors). Treatment starts with bevacizumab. If this is not sufficiently effective, the patient is switched to a second and possibly a third anti-VEGF inhibitor; aflibercept and/or ranibizumab. These products inhibit the production of the new poor-quality veins, stopping fluid and blood leakage and improving vision. Faricimab, administered as an injection into the eye, works similarly.

Registered indication
Faricimab (Vabysmo®) is indicated for the treatment of adult patients with visual impairment due to macular oedema secondary to retinal venous occlusions (RVO), venous branch occlusion (branch RVO) or retinal venous stem occlusion (central RVO).

In addition, faricimab is registered and reimbursed for wet age-related macular degeneration (wAMD) and visual impairment due to diabetic macular oedema (DMO). These indications are not taken into consideration in this assessment.

Claim by the marketing authorisation holder
Faricimab (Vabysmo®) has at least an equal value to aflibercept for the

registered indication.

National Health Care Institute
Care
Medicinal Products

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Our reference
2025004635

Package advice

The National Health Care Institute recommends that faricimab (Vabysmo®) be included in the basic healthcare package for the treatment of adult patients with visual impairment due to macular oedema secondary to retinal venous occlusions (RVO), venous branch occlusion (branch RVO) or retinal venous stem occlusion (central RVO).
The National Health Care Institute has established that, in the aforementioned indication, faricimab meets the legal criterion of 'established medical science and medical practice' and that there is an equal value compared to aflibercept 2 mg.
The professional association sees a place for treatment with aflibercept, ranibizumab and faricimab after 1st treatment option bevacizumab.
The National Health Care Institute recommends that faricimab should only be included in the package if it does not lead to additional costs compared to the costs associated with current aflibercept or Ranibizumab treatment. We explain the preparation of this package advice below.

General

At your request, the National Health Care Institute assesses whether care should be part of the standard health insurance package from the perspective of the basic healthcare package paid from joint premiums.

The National Health Care Institute assesses on the basis of the four package criteria[1]: effectiveness[2], cost-effectiveness, necessity and feasibility. The Scientific Advisory Board (WAR) advises the National Health Care Institute on the (scientific) basis and the conclusion of the assessment. Stakeholders are consulted during the process.

Comprehensive weighting of package criteria

Effectiveness

Established medical science and medical practice

Faricimab has been studied in adult patients with visual impairment due to macular oedema secondary to venous occlusion in the BALATON and COMINO studies. In these two almost identical randomised, blinded clinical studies (RCTs), faricimab shows a similar clinically relevant improvement in vision and quality of life as aflibercept 2 mg[3]. The professional association sees both medical products as a treatment after bevacizumab. Although the study was conducted in treatment-naive patients, the National Health Care Institute has sufficient confidence, based on the consistency across all critical and important outcomes, in an equivalent value to aflibercept 2 mg as a treatment following bevacizumab. However, the National Health Care Institute notes that it cannot comment on the usefulness of sequential treatments.

Cost-effectiveness

Due to its equal value, the National Health Care Institute has not assessed its

[1] Real-world package management 4 (2023). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

[2] Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via www.zorginstituutnederland.nl.

[3] Both a 2 and 8 mg dose are available, but the study has only compared faricimab with 2 mg aflibercept

cost-effectiveness.

Budget-impact analysis
The total costs per patient per year amount to €6,643 in the first year and €4,380 in subsequent years. The professional association has indicated that if bevacizumab is not effective enough, patients should be switched to a second, third and possibly a fourth anti-VEGF inhibitor, namely aflibercept, ranibizumab and/or faricimab. The order of treatment has an impact on the macro costs, but hardly on the budget impact for faricimab.
In the baseline scenario, patients are first treated with aflibercept 2 mg, and only patients who do not respond to this are switched to ranibizumab and/or faricimab. In this scenario, the National Health Care Institute estimates that 305 patients per year will be treated with faricimab for this indication in year 3 after inclusion in the health insurance package, resulting in macro costs of €3.2 million. Taking into account ranibizumab substitution, the budget impact will be €1.1 million in year 3. In particular, there is uncertainty about market penetration. The additional costs are due to the higher list price of faricimab compared to ranibizumab.
In an alternative scenario, after bevacizumab, if treatment was not sufficiently effective, it would be switched to aflibercept 2 mg, ranibizumab and/or faricimab. Due to a significantly higher number of patients for faricimab in this scenario, the macro costs significantly increase, i.e. to €37.1 million. However, the budget impact remains almost the same at €1.2 million. The reason for this is that ranibizumab is being substituted with a lower list price and aflibercept 2 mg with a slightly higher list price.

The estimated additional costs are based on list prices. The National Health Care Institute recommends that faricimab should only be included in the insured package for this indication if it does not lead to additional costs compared to the costs associated with the current treatment with aflibercept 2 mg or ranibizumab. Aflibercept 2 mg and ranibizumab have not been assessed by the National Health Care Institute and have been included in the health insurance package via the route of the healthcare insurers. Faricimab has not been placed in the lock procedure for two other registered indications. The anti-VEGF products are in a market with competing products (confidential net prices between hospital and MAH). This applies to the three registered indications of the anti-VEGF products, namely the wAMD, DME and RVO indication for which faricimab has now been evaluated. The National Health Care Institute notes that the patent for ranibizumab has lapsed and the patent for aflibercept (Eylea®) will end in November 2025. The price of aflibercept is expected to decrease with the introduction of biosimilars.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as annexes (pharmacotherapeutic report, budget-impact analysis).

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Care
Medicinal Products

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Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

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