SUMMARY

faricimab

VABYSMO 120 mg/mL

solution for injection

Inclusion on list

Adopted by the Transparency Committee on 18 December 2024

Summary of opinion

Favourable opinion for reimbursement in the treatment of adult patients with reduced visual acuity due to macular oedema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Transparency Committee's conclusions

Clinical Benefit

- Retinal vein occlusion is an eye condition affecting the retina and, at its centre, the macula, which is responsible for detailed vision. It leads to circulatory delay, infiltrations and macular oedema, responsible for a decrease in visual acuity. The functional prognosis depends on the clinical form of the retinal vein occlusion. There are two main forms: an ischaemic form with a poor visual prognosis and a well-perfused (oedematous) form with a better prognosis.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a first-line treatment in adult patients with macular oedema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the partial response to the identified need given:
  - the lack of evidence of an additional impact compared to aflibercept on morbidity based on a functional endpoint (visual acuity) after 24 weeks of treatment, due to evidence of non-inferiority compared to aflibercept, without evidence of superiority,
  - the lack of evidence of an impact on quality of life,
  - the lack of evidence of an additional impact of the organisation of care or on the patient's care or life pathway,

VABYSMO (faricimab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of VABYSMO 120 mg/mL (faricimab) solution for injection is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of VABYSMO 120 mg/mL (faricimab) solution for injection in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- evidence of the non-inferiority of VABYSMO (faricimab) compared to EYLEA (aflibercept) for the mean change in best corrected visual acuity after 24 weeks of treatment, using a fixed treatment regimen of one injection every four weeks, in two phase 3, multicentre, randomised, double-masked studies, one in adult patients with macular oedema secondary to branch retinal vein occlusion (BRVO) and the other in adult patients with macular oedema secondary to central retinal vein occlusion or hemiretinal vein occlusion (CRVO/HRVO),
- the short-term (24 weeks) safety profile of faricimab similar to that of aflibercept and similar to that observed in the other indications, marked, in particular, by ocular adverse events and adverse events related to the pharmacotherapeutic group (such as intraocular inflammation, retinal vasculitis or occlusive retinal vasculitis, and thromboembolic events, monitored in the context of the risk management plan),

but:

- the lack of evidence of the superiority of VABYSMO (faricimab) compared to EYLEA (aflibercept) in terms of change in visual acuity after 24 weeks,
- the absence of longer-term comparative efficacy and safety data demonstrating an advantage of VABYSMO (faricimab) compared to EYLEA (aflibercept), particularly in terms of reduction in the number of injections during the individualised treatment phase,

the Committee deems that VABYSMO (faricimab) solution for injection provides no clinical added value (CAV V) compared to EYLEA (aflibercept) in the treatment of adult patients with macular oedema secondary to BRVO or CRVO.