SUMMARY

faricimab

VABYSMO 120 mg/Ml,

solution for injection

New indication

Adopted by the Transparency Committee on 18 January 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement only in “the treatment of adult patients with visual impairment due to diabetic macular oedema (DME), in the event of diffuse forms or leakages close to the centre of the macula, in adults with a visual acuity of ≤ 5/10 and in whom diabetes management has been optimised.”

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

VABYSMO (faricimab) is a first-line treatment of visual impairment due to diabetic macular oedema in the event of diffuse forms or leakages close to the centre of the macula, in adults with a visual acuity of less than or equal to 5/10 and in whom diabetes management has been optimised.

The choice between anti-VEGF therapies as first-line treatment is left to the decision of the ophthalmologist, who should take into account the ophthalmological characteristics of the treated eye [history of glaucoma or ocular hypertonia, lens status (phakic or pseudophakic), history of vitrectomy], the diabetic retinopathy stage, as well as the patient’s cardiovascular and cerebrovascular history, age and capacities to comply with treatment.

Special recommendations

> The Committee recommends exception drug status.

Transparency Committee's conclusions

Clinical Benefit

- Diabetic macular oedema is a complication of diabetic retinopathy. It is asymptomatic but progresses gradually to visual impairment and blindness, resulting in disability and a marked deterioration in quality of life.
- VABYSMO 120 mg/mL (faricimab) solution for injection is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives.
- VABYSMO (faricimab) is a first-line treatment of visual impairment due to diabetic macular oedema in the event of diffuse forms or leakages close to the centre of the macula, in adults with a visual acuity of less than or equal to 5/10 and in whom diabetes management has been optimised (see section 5.1 Role in the care pathway).

Public health benefit

Considering:

- the seriousness of the disease and its prevalence (3% of diabetic patients),
- the identified partially met medical need,
- the partial response to the identified partially met medical need, given:
  - the absence of a demonstrated additional impact compared to aflibercept on morbidity based on a functional endpoint (visual acuity) after one year of treatment, due to evidence of non-inferiority compared to aflibercept, without evidence of a superiority,
  - the lack of robust evidence of an impact on quality of life,
  - the lack of evidence of an additional impact on the organisation of care or on the patient's care and life pathway,

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

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

- **substantial, in adults, for the treatment of visual impairment due to diabetic macular oedema, in the case of diffuse forms or leakages near the centre of the macula in patients with visual acuity of less than or equal to 5/10 and for whom the management of diabetes has been optimised;**
- **insufficient in other cases to justify public funding in view of the available alternatives.**

The Committee issues the following opinions for VABYSMO (faricimab) 120 mg/mL solution for injection:

- **favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use for the**

treatment of visual impairment due to diabetic macular oedema, in the case of diffuse forms or leakages close to the centre of the macula, in adult patients with visual impairment of 5/10 or less, and in whom the management of diabetes has been optimised, and at the marketing authorisation dosages;

- **unfavourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in other cases.**

➔ **Recommended reimbursement rate: 65%**

Clinical Added Value

Considering:

- the results of two randomised, double-blind, phase 3 trials having compared VABYSMO (faricimab) with EYLEA (aflibercept), in adults with visual impairment due to DME (BCVA of between 78 and 23 ETDRS letters inclusive) involving the centre of the macula, in whom the management of diabetes has been optimised, and having demonstrated the non-inferiority of faricimab (fixed regimen and personalised regimen) compared to aflicbercept (fixed regimen) after one year of treatment, based on functional endpoints in terms of:
  - change in visual acuity compared to baseline (primary endpoint) in the two studies;
  - proportion of patients who achieved an at least 2-step improvement in diabetic retinopathy severity on the ETDR-DRSS scale compared to baseline (ranked secondary endpoint), in a single study;
- the lack of robust evidence of an additional impact on quality life or on the patient's care and life pathway;
- safety comparable to that recorded for aflibercept;

the Committee deems that VABYSMO (faricimab) solution for injection provides no clinical added value (CAV V) compared to EYLEA (aflibercept), in adults, for the treatment of visual impairment due to diabetic macular oedema in the event of diffuse forms or leakages close to the centre of the macula, in adults with a visual acuity of less than or equal to 5/10 and in whom diabetes management has been optimised.