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 “the treatment of neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults”.

What therapeutic improvement?

No clinical added value in the therapeutic strategy.

Role in the care pathway?

VABYSMO (faricimab) is a first-line treatment for neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults.

The choice between anti-VEGF therapies as first-line treatment is left to the decision of the ophthalmologist.

Special recommendations

The Committee recommends exception drug status.

Transparency Committee's conclusions

Clinical Benefit

- Age-related macular degeneration (AMD) is the leading cause of visual disability in France in patients over the age of 50. Among severe forms of AMD, wet or neovascular forms are responsible for the largest number of severe visual acuity reductions.
- VABYSMO 120 mg/mL (faricimab) solution for injection is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives.
- It is a first-line treatment for neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults.

Public health benefit

Considering:

- the seriousness of the disease, progressing to visual disability, and its incidence,
- the 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 additional 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 (faricimab) 120 mg/mL solution for injection is:

- **substantial in the treatment of neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults.**
- **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 in the treatment of neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults, and at the MA 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:

- evidence of the non-inferiority of VABYSMO (faricimab, using a QW8/QW12/QW16 personalised administration regimen) compared to EYLEA (aflibercept, using a Q8W fixed administration regimen), based on the functional endpoint of visual acuity, in two randomised, double-blind, phase 3 trials in adults with neovascular (wet) age-related macular degeneration (AMD) and who are treatment-naïve;
- the absence of a comparison between faricimab administered using a personalised regimen and aflibercept administered using a "Treat-and-Extend" regimen;
- the lack of robust evidence of an additional impact on quality life or on the patient's care and life pathway (particularly in terms of a reduction in the frequency of injections) compared to the available alternatives;
- 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) solution for injection in pre-filled syringe in the treatment of neovascular (wet) retrofoveal age-related macular degeneration (AMD) in adults.