Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version.

SUMMARY

faricimab

VABYSMO 120 mg/mL

solution for injection in pre-filled syringe

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement in:

- **neovascular** (wet) retrofoveal age-related macular degeneration (nAMD);
- 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**;
- 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).

Unfavourable opinion for reimbursement in the other clinical situations for the indications relating to nAMD and visual impairment due to DME.

No clinical added value of the new form compared to the VABYSMO 120 mg/mL (faricimab) solution for injection in vial form already available.

Transparency Committee's Conclusions

Clinical Benefit

AMD

➔ 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.

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- VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a first-line treatment for neovascular (wet) retrofoveal age-related macular degeneration (nAMD) in adults, in view of the available alternatives.

Public health benefit

VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe is unlikely to have an additional impact on public health compared to the solution for injection in vial form.

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

- **substantial in the treatment of neovascular (wet) retrofoveal age-related macular degeneration (nAMD) in adults,**
- **insufficient in other cases to justify public funding in view of the available alternatives.**

The Committee issues the following opinions for VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe:

- **favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the treatment of neovascular (wet) retrofoveal age-related macular degeneration (nAMD) in adults, and at the MA dosages;**
- **unfavourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in other cases.**

DME

- 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 in pre-filled syringe 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.

➔ Public health benefit

VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe is unlikely to have an additional impact on public health compared to the solution for injection in vial form.

Considering all of these elements, the Committee deems that the clinical benefit of VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe 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 list of covered drugs for outpatients and the list of covered drugs for inpatients 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 MA dosages;**
- **unfavourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in other cases.**

Macular oedema secondary to retinal vein occlusion

- 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.
- VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe 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), in view of the available alternatives.

➔ Public health benefit

VABYSMO 120 mg/mL (faricimab) solution for injection in pre-filled syringe is unlikely to have an additional impact on public health compared to the solution for injection in vial form.

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 pre-filled syringe 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

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the form already listed.