SUMMARY

efgartigimod alfa

VYVGART 1,000 mg

solution for injection

Inclusion on list: First listing

Original French opinion adopted by the Transparency Committee on 10 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement only "as an add-on to standard therapy, including first-line immunosuppressants, for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, who remain symptomatic".

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee's conclusions

Clinical Benefit

- Myasthenia is an incapacitating, rare, serious autoimmune disease causing fluctuating muscle weakness and excessive fatigability, which can impair patients' quality of life and autonomy. Severe forms may progress towards life-threatening myasthenic crises.
- The proprietary medicinal product VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation as an add-on to standard therapy, including first-line immunosuppressants, is a curative background therapy.
- the efficacy/adverse effects ratio is:
  - high as an add-on to standard therapy, including first-line immunosuppressants, for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, who remain symptomatic.
  - not established in the other populations of the MA indication due to a lack of data.
- There are therapeutic alternatives.
- The role of VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation is identical to that of VYVGART 20 mg/mL (efgartigimod alfa) concentrate for solution for infusion.

VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation is a first-line treatment as an add-on to standard therapy, including first-line immunosuppressants, for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, who remain symptomatic despite well managed treatment.

However, within the scope included in the MA but not retained for reimbursement, VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation has no role in such a situation.

➔ Public health benefit

Considering:

- the seriousness of the disease and its low prevalence,
- the partially met medical need,
- the partial response to the identified need, with:
  - the lack of evidence of an additional impact on morbidity and mortality in view of the limited data available,
  - the lack of evidence of an additional impact on quality of life,
  - the lack of evidence of an additional impact on the organisation of care and the patient's care and life pathway,

VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation is:

- **substantial only as an add-on to standard therapy, including first-line immunosuppressants, for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, who remain symptomatic,**
- **insufficient to justify public funding cover in view of the available alternatives in the other clinical situations of the MA.**

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use as an add-on to standard therapy, including first-line immunosuppressants, for the treatment of generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive, who remain symptomatic, and at the MA dosages.

The Committee issues an unfavourable opinion for inclusion in the list of covered drugs for inpatients approved for use in the other clinical situations of the MA.

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

Clinical Added Value

Considering:

- **demonstration of the non-inferiority of efgartigimod alfa administered by the subcutaneous route compared to administration by the IV route, in terms of pharmacokinetics (percentage decrease in total IgG levels between baseline and day 29), demonstrated in an open-label study in patients with generalised myasthenia gravis (gMG), and the methodological reservations raised,**
- **the absence of comparative efficacy data versus efgartigimod IV,**
- **the similar short-term safety profile between the two administration routes, apart from injection site reactions, which were more common with SC administration of efgartigimod alfa compared to IV administration,**
- **uncertainties with respect to long-term safety,**
- **the absence of a formally demonstrated impact in terms of improvement in quality of life with the subcutaneous formulation compared to the IV formulation,**

the Transparency Committee considers that VYVGART (efgartigimod alfa) 1,000 mg solution for injection in subcutaneous formulation provides no clinical added value (CAV V) compared to the proprietary medicinal product VYVGART 20 mg/mL (efgartigimod alfa) concentrate for solution for infusion.