Original French opinion adopted by the Transparency Committee.

The legally binding text is the original French opinion version.

SUMMARY

guselkumab

TREMFYA 100 mg and 200 mg

solution for injection in pre-filled syringe or pre-filled pen (100 mg or 200 mg) or concentrate for solution for infusion (200 mg)

Inclusion on list

Adopted by the Transparency Committee on 16 July 2025

Summary of opinion

Favourable opinion for reimbursement only in the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to conventional therapy, at least one prior TNFα antagonist and vedolizumab.

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

Transparency Committee's conclusions

Clinical Benefit

- Seriousness of the disease: ulcerative colitis (UC) is a chronic inflammatory bowel disease (IBD) that results in severe chronic bloody diarrhoea, progressing in flare-ups. It leads to a marked deterioration in quality of life and exposes patients to serious complications: acute colitis, dysplasia and colon cancer.
- This medicinal product is a symptomatic and preventive treatment for ulcerative colitis flares.
- The efficacy/adverse effects ratio of guselkumab (TREMFYA) in adults in the treatment of UC is moderate, with, in particular, an effect compared to placebo that is at best moderate on clinical remission, and given that the effect size in comparison with placebo appears to be lower in the subpopulation of patients having failed at least one prior TNFα antagonist or vedolizumab or tofacitinib. The safety profile appears to be good based on the available data.
- This is a third-line treatment in view of the therapies available. There are medicinal alternatives for second- and third-line therapy.

➔ Public health benefit

Considering:

- the seriousness and prevalence of ulcerative colitis, a serious and incapacitating chronic disease with high morbidity due to the frequency of acute flare-ups, its complications and recourse to surgery. UC also significantly impairs quality of life,
- the partially met medical need, particularly in third-line treatment,
- the partial response to the identified need given:
  - the lack of evidence of an additional impact on morbidity and mortality, due to an effect size compared to placebo that is at best moderate on clinical remission, an effect on quality of life determined only in comparison with placebo, and the absence of a comparison with the second- and third-line medicinal alternatives,
  - the lack of evidence of an additional impact on the organisation of care, and the care or life pathway for patients or their families, in view of the available alternatives,

TREMFYA (guselkumab) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of TREMFYA (guselkumab) is:

- **moderate only in the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to conventional therapy, at least one prior TNFα antagonist and vedolizumab,**
- **insufficient to justify public funding in view of the available alternatives in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of TREMFYA (guselkumab) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only within the scope retained and at the MA dosages,**
- **an unfavourable opinion for inclusion of TREMFYA (guselkumab) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

➔ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 30%

Clinical Added Value

Considering:

- **the methodological quality of the two pivotal studies (controlled, randomised, double-blind, relevant choices of outcome measures including quality of life, sample size), but given that the choice of placebo is regrettable, particularly in patients with no prior biologic therapy, and that the efficacy was assessed in a heterogeneous population including biologic therapy-naive and non-naive patients;**
- **evidence of superiority of guselkumab versus placebo, with an effect size that is at best moderate on clinical remission in the overall study population; the lack of evidence of an effect on referral for colectomy;**

- **the lack of comparative data versus TNFα antagonists in patients having responded inadequately to a conventional disease-modifying therapy and with no prior TNFα antagonist therapy, and versus vedolizumab (ENTYVIO), despite these comparisons being possible;**
- **and the good safety profile of guselkumab,**

the Committee deems that TREMFYA (guselkumab) provides no clinical added value (CAV V) in the current care pathway, which includes clinically relevant comparators.