SUMMARY

mirikizumab

OMVOH 100 mg and 300 mg

solution for dilution for injection (300 mg strength); solution for injection in pre-filled syringe or pre-filled pen (100 mg strength)

Initial inclusion

Original French opinion adopted by the Transparency Committee on 31 January 2024

The legally binding text is the original French opinion version

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.
- OMVOH (mirikizumab) is a symptomatic medicinal product for UC and a preventive treatment for recurrences.
- The efficacy/adverse effects ratio of mirikizumab (OMVOH) 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 bowel urgency, 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 treatment. The safety profile appears to be good based on the available data.
- OMVOH (mirikizumab) is a third-line treatment for UC, following the failure of conventional therapy, at least one prior TNFα antagonist and vedolizumab.

➔ 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 causes a marked impairment in quality of life;
- the partially met medical need, including in the third-line treatment of UC,
- the partial response to the identified need, with:
  - an effect size compared to placebo that is at best moderate on clinical remission, and the absence of comparison with second-line and third-line alternatives,
  - the lack of a demonstrated additional impact on morbidity and mortality or quality of life,
  - the lack of an expected additional impact on the organisation of care and the patient's care and/or life pathway,

OMVOH 300 mg solution for injection and OMVOH 100 mg solution for injection (mirikizumab) are unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of OMVOH 300 mg solution for injection and OMVOH 100 mg solution for injection (mirikizumab) is:

- **moderate in the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, 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:

- **favourable for inclusion of OMVOH 300 mg solution for injection and OMVOH 100 mg solution for injection (mirikizumab) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for the indication and at the MA dosages;**
- **unfavourable for inclusion of OMVOH 300 mg solution for injection and OMVOH 100 mg solution for injection (mirikizumab) in both 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: 65%.

Clinical Added Value

Considering:

- the methodological quality of the two pivotal studies (controlled, randomised, double-blind, relevant choices of outcome measures including bowel urgency affecting 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 (majority) and non-naive patients;
- demonstration of the superiority of mirikizumab compared to placebo, with an at best moderate effect size on clinical remission;
- the lack of evidence of an effect on recourse to colectomy and on quality of life,
- 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 mirikizumab,

The Committee deems that OMVOH 300 mg solution for injection and OMVOH 100 mg solution for injection (mirikizumab) provide no clinical added value (CAV V) in the current care pathway.