SUMMARY

etrasimod

VELSIPITY 2 mg

film-coated tablets

First listing

Adopted by the Transparency Committee on 4 September 2024

Summary of opinion

Favourable opinion for reimbursement only in the treatment of patients 16 years of age and older 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: 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 treatment for ulcerative colitis and a preventive treatment for recurrences.
- The efficacy/adverse effects ratio of etrasimod is low in the population for which funding is requested in third-line treatment and is still to be established in second-line treatment.
- There are medicinal alternatives for second- and third-line therapy. However, the role of etrasimod is still to be established in second-line treatment and is inadequately established (exploratory results in a small number of patients) in third-line treatment in view of the available therapies.

➔ **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 response to the identified need given:
  - an effect size compared to placebo that is at best moderate on clinical remission,
  - the lack of comparison with second- and third-line medicinal alternatives,
  - the lack of evidence of an additional impact on morbidity and mortality or quality of life,
  - the lack of evidence of an impact on the organisation of care, and the care or life pathway for patients or their families,

VELSIPITY 2 mg film-coated tablets (etrasimod) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of VELSIPITY 2 mg film-coated tablets is:

- **moderate in the treatment of adult patients with moderately to severely active ulcerative colitis 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 VELSIPITY 2 mg film-coated tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use at the MA dosages only "in the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to conventional therapy, at least one prior TNFα antagonist and vedolizumab";**
- **an unfavourable opinion for inclusion of VELSIPITY 2 mg film-coated tablets 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:

- data from the two pivotal phase 3 studies, ELEVATE UC12 and ELEVATE UC52, which, although comparative and randomised, were conducted versus placebo, despite the fact that a comparison of etrasimod (VELSIPITY 2 mg film-coated tablets) with a clinically relevant comparator both as second-line treatment (TNFα antagonist, vedolizumab) and as third-line treatment (in particular, ustekinumab) would have been possible but was not conducted by the pharmaceutical company, and the unusual conduct of just one study in maintenance therapy,

- the absence of efficacy and safety data enabling estimation of the relative efficacy and potential contribution of VELSIPITY 2 mg film-coated tablets (etrasimod) compared to these clinically relevant comparators,
- the inadequately established efficacy of etrasimod (VELSIPITY 2 mg film-coated tablets) in patients requiring third-line treatment and for whom the pharmaceutical company is requesting funding (exploratory analysis in a small subgroup),
- the safety profile of etrasimod (VELSIPITY 2 mg film-coated tablets) established on the basis of limited exposure,

the Committee deems that VELSIPITY 2 mg film-coated tablets provides no clinical added value (CAV V) in the current care pathway.