HAUTE AUTORITÉ DE SANTÉ

ASSESS HEALTH TECHNOLOGIES

OPINION ON MEDICINAL PRODUCTS

vedolizumab

ENTYVIO 300 mg,

powder for concentrate for solution for infusion

New indication(s)

Adopted by the Transparency Committee on 19 October 2022

SUMMARY

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Considering all of this information and after discussions and a vote, the Committee deems that for the indication extension for the "***Treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis, and have had an inadequate response with or lost response to antibiotic therapy***":

Clinical Benefit

- Disease severity: in addition to symptom onset, patients with chronic pouchitis, a rare condition failing to respond to conventional treatment, have persistent symptoms potentially resulting in pouch failure. This may have an impact on the patient's work, home and social life. Therefore, there may be a significant impact on patients' quality of life.
- The proprietary medicinal product ENTYVIO (vedolizumab) is a curative and symptomatic medicinal product.
- The efficacy/adverse effect ratio of vedolizumab has yet to be established: in the short term, the effect size versus placebo is questionable, and there is no demonstrated clinical benefit for patients with pouchitis.
- Availability of alternative: there is no clinically relevant comparator with a marketing authorisation for the assessed indication. For adult patients failing to respond, or no longer responding, to antibiotic therapy, short-term treatment (8 weeks) of pouchitis with oral corticosteroids (budesonide, beclomethasone) is an alternative to antibiotic therapy, but only in the short term (8 weeks). TNFα inhibitors (infliximab, adalimumab as an alternative) are currently used for long term-treatment (off-label), but the benefit is poorly established.

➔ It is not possible to define the role of the proprietary medicinal product ENTYVIO (vedolizumab) in the therapeutic strategy given the lack of clinical relevance of the efficacy findings of the EARNEST study.

➔ Public health benefit

Considering:

- the severity of the disease;
- an insufficiently met medical need;
- the non-established response to the identified need with:
  - an additional impact on morbidity-mortality that has yet to be established, on account of an established efficacy of vedolizumab merely versus placebo, only at 14 weeks, and of uncertain clinical efficacy;
  - the lack of established additional impact on quality of life;
  - the lack of expected additional impact on delivery of care; note that intravenous vedolizumab must be administered in a medical setting equipped to treat acute hypersensitivity reactions including anaphylaxis;
  - the lack of expected impact on the care and/or life pathway;

ENTYVIO (vedolizumab) is not likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the actual clinical benefit (ACB) of ENTYVIO (vedolizumab) is insufficient to justify public funding for the extension of the marketing authorisation indication

The Committee disapproves inclusion in the list of proprietary medicinal products approved for community use for the extension of the marketing authorisation indication and at the marketing authorisation dosages.