SUMMARY

dupilumab

DUPIXENT 300 mg

solution for injection in pre-filled syringe or pre-filled pen

First listing

Adopted by the Transparency Committee on 27 November 2024

Summary of opinion

Favourable opinion for reimbursement in the following indication extension: "treatment ofeosinophilic oesophagitis in adults and adolescents aged 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy".

Transparency Committee's conclusions

Clinical Benefit

In eosinophilic oesophagitis (EoE):

- Seriousness of the disease: generally, EoE is not usually serious, with spontaneously fluctuating symptoms. In adolescents and adults, it primarily manifests as dysphagia and food impactions. It is generally not serious and progresses very slowly, even when it does not respond to conventional treatments (PPIs and topical corticosteroids).
- This is a symptomatic medicinal product (dysphagia).
- The efficacy/adverse effects ratio of dupilumab in the treatment of eosinophilic oesophagitis in adults and adolescents aged 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy is low.
- This is a third-line treatment in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease eligible for medical treatment (therefore excluding complications), its prevalence and incidence;
- the medical need partially met by food exclusion diets;
- the inadequately established response to the identified need given:
  - the lack of solid data establishing its clinical value in the event of failure of conventional PPI and topical corticosteroid treatment,

- the absence of a demonstrated impact on complications and quality of life, and of an expected additional impact on the organisation of care, and the care and life pathway for patients or their families;

DUPIXENT (dupilumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of DUPIXENT 300 mg solution for injection (in pre-filled syringe or pre-filled pen) is low in the treatment of eosinophilic oesophagitis in adults and adolescents aged 12 years and older, weighing at least 40 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy.

The Committee issues a favourable opinion for inclusion of DUPIXENT 300 mg solution for injection (in pre-filled syringe or pre-filled pen) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- evidence of the superiority of dupilumab 300 mg solution for injection compared to placebo in two randomised phase 3 studies in patients who had mostly failed PPI therapy, but half of whom were not cortico-resistant, making it difficult to assess the benefit in the population concerned by the indication (cortico-resistant), with the size of the population also being limited,
- an at best modest effect size on the DSQ scale (ref. 1) relating to dysphagia,
- the debatable clinical relevance of the co-primary endpoint concerning the proportion of patients with a peak oesophageal intraepithelial eosinophil count of ≤ 6 EOS/HPF,
- the absence of a demonstrated effect on food impactions and on progression to fibrosis of the oesophageal mucosa,
- a long-term safety profile that remains to be determined at the dosage recommended in this indication, double that recommended in the other MA indications,
- the lack of demonstrated impact on quality of life,

the Transparency Committee considers that DUPIXENT 300 mg solution for injection (in pre-filled syringe or pre-filled pen) provides no clinical added value (CAV V) in the care pathway for the treatment of eosinophilic oesophagitis in adults and adolescents aged 12 years and older, weighing at least 40 kg.

© Haute Autorité de santé – November 2024