HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
11 DECEMBER 2019

dupilumab

DUPIXENT 200 mg solution for injection in pre-filled syringe and pen
DUPIXENT 300 mg solution for injection in pre-filled syringe

New indication

Key points

Favourable opinion for reimbursement in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fractional exhaled nitric oxide (FeNO), who are inadequately controlled with high-dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment.

What therapeutic improvement?

Slight therapeutic improvement.

Role in the care pathway?

The main objective of pharmacological treatment of asthma in adults and adolescents is to ensure durable maintenance of asthma control, including the reduction of symptoms, the prevention of exacerbations, the improvement of respiratory function, the reduction of restrictions in everyday activities and the limitation of adverse reactions related to pharmacological treatments.

The GINA defines fives treatment steps, with severe asthma corresponding to step 4 (disease requiring the use of maintenance treatment by a combination of moderate or high-dose ICS and LABA, potentially supplemented with one or more other bronchodilators or anti-inflammatories, and step 5 (disease not controlled by step 4 treatment, requiring maintenance treatment, add-on treatment with oral or injectable corticosteroids or monoclonal antibody therapy with anti-IgE [omalizumab] in the event of allergic asthma or anti-IL5 [benralizumab, mepolizumab, reslizumab] in the event of eosinophilic asthma or anti-IL4 [dupilumab] in the event of asthma associated with type 2 inflammation).

Role of the medicinal product in the care pathway

DUPIXENT (dupilumab) is a new therapeutic alternative in patients with severe asthma. Patients whose asthma is not controlled due to inappropriate maintenance treatment, treatment compliance problems, comorbidities or untreated exacerbating risk factors do not fall within this scope.

In the absence of any direct comparison between DUPIXENT and biologic therapies (CINQAERO, FASENRA, NUCALA, XOLAIR), the role of DUPIXENT among the other biologic therapies available in severe asthma remains to be specified.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

- Uncontrolled severe asthma has a major impact on quality of life and is associated with a risk of potentially life-threatening severe exacerbations.
- DUPIXENT is part of a symptomatic maintenance treatment regimen in patients 12 years and older with uncontrolled severe asthma with type 2 inflammation.
- The efficacy/adverse effects ratio is high in combination with a high-dose ICS and another maintenance treatment for asthma in the population of the MA indication, i.e., adults and adolescents 12 years and older with inadequately controlled severe asthma with type 2 inflammation characterised by raised blood eosinophils ≥ 150 cells/µl and/or raised FeNO ≥ 20 ppb.
- This proprietary medicinal product is a new therapeutic option in patients with severe asthma.
- There are therapeutic alternatives.

Public health impact:

Considering:

- the seriousness of severe asthma,
- its prevalence,
- the partially met medical need in patients with uncontrolled severe asthma,
- the lack of response to the identified need in the absence of any expected additional impact on morbidity and mortality and/or the quality of life of patients,
- the lack of expected impact on the organisation of care,

DUPIXENT is unlikely to have an impact on public health.

Considering these elements, the Committee deems that the clinical benefit of DUPIXENT is substantial in the indication "in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO (see section 5.1 of the SPC), who are inadequately controlled with high-dose ICS plus another medicinal product for maintenance treatment."

The Committee issues a favourable opinion for inclusion of DUPIXENT 200 mg 300 mg in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication "in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised FeNO (see section 5.1 of the SPC), who are inadequately controlled with high-dose ICS plus another medicinal product for maintenance treatment."

- **Recommended reimbursement rate: 65%**

01.1 Clinical Added Value

Considering:

- **demonstration in the ITT population (broader population than that of the MA) of three placebo-controlled trials of a reduction, compared to placebo, of asthma exacerbations in patients with non-corticosteroid-dependent asthma and of daily oral corticosteroid doses in patients requiring continuous oral corticosteroid therapy,**
- **the results available in the MA population derived from post-hoc analyses that are similar to those in the broader ITT population;**
- **the lack of demonstration of any superiority versus placebo for quality of life and asthma control;**
- **the partially met medical need in patients with uncontrolled severe asthma and the risks associated with exacerbations;**

DUPIXENT provides a minor clinical added value (CAV IV), like CINQAERO, FASENRA, NUCALA and XOLAIR, in the treatment of severe asthma with type 2 inflammation in adults and adolescents 12 years and older who are inadequately controlled with high dose ICS plus another medicinal product for maintenance treatment.