OPINION RELATIVE TO MEDICINAL PRODUCTS

Mépolizumab
NUCALA 100 mg

powder for solution for injection in vial, solution for injection in pre-filled syringe and solution for injection in pre-filled pen

Re-evaluation and new presentation

Adopted by the Transparency Committee on 29 June 2022

SUMMARY

The legally binding text is the original French opinion version

- **Asthma**
- **Sectors: Retail and hospital**

Key points

Favourable opinion for reimbursement as an add-on treatment for severe refractory eosinophilic asthma in adults meeting the following criteria:

– a **blood eosinophil count of ≥ 150/µL** within the past 12 months;

AND

- at least two episodes of asthma exacerbations having required oral corticosteroid therapy (≥ 3 days each) in the past 12 months despite maintenance therapy combining high-dose inhaled corticosteroids and a long-acting bronchodilator (LABA);
- OR oral corticosteroid therapy for at least 6 months in the past 12 months.

Unfavourable opinion for reimbursement in other clinical situations as an add-on treatment for severe refractory eosinophilic asthma in adults.

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

asthma attacks and exacerbations, the reduction of the impact of the condition on everyday activities, at the same time limiting adverse reactions related to pharmacological treatments.

The therapeutic management is adapted to the severity of the disease. International consensus has identified 5 severity steps with treatment escalation in the event of non-control or partial control of asthma. Severe asthma corresponds to steps 4 and 5:

– step 4: asthma requiring the use of maintenance therapy combining a moderate-dose ICS and formoterol (preferential maintenance therapy);
– step 5: uncontrolled step 4 asthma requiring recourse to maintenance therapy with a high-dose ICS and formoterol, with a biologic therapy as add-on therapy if necessary, depending on the asthma phenotype.

Role of the medicinal product in the care pathway

According to the ERS / ATS (European Respiratory Society/American Thoracic Society) and EAACI (European Academy of Allergy and Clinical Immunology) guidelines, the eosinophil count should be ≥ 150/µL for the initiation of treatment with NUCALA (mepolizumab). This count should be ≥ 150/µL or ≥ 300/µL for the initiation of treatment with NUCALA (mepolizumab) according to the GINA.

The Committee defines those patients liable to benefit from NUCALA (mepolizumab) as follows:

– patients with a blood eosinophil count of ≥ 150/µL within the past 12 months;
AND
- patients having had at least two episodes of asthma exacerbations having required oral corticosteroid therapy (≥ 3 days each) in the past 12 months despite maintenance therapy combining high-dose inhaled corticosteroids and a long-acting bronchodilator (LABA);
- OR patients treated with oral corticosteroid therapy for at least 6 months in the past 12 months.

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 NUCALA (mepolizumab) and biologic therapies (FASENRA [benralizumab], DUPIXENT [dupilumab], XOLAIR [omalizumab]), the role of NUCALA (mepolizumab) among the other biologic therapies available in severe asthma remains to be specified.

Committee's conclusions

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

- Inadequately controlled severe asthma exposes patients to a risk of the occurrence of severe exacerbations, which can lead to hospitalisation and be life-threatening.
- This proprietary medicinal product is a symptomatic maintenance therapy in adult patients with severe refractory eosinophilic asthma.
- The efficacy/adverse effects ratio of this proprietary medicinal product is high in the patients defined in the context of the care pathway.
- There are therapeutic alternatives (other biologic therapies).
- The role of NUCALA (mepolizumab) is as a therapeutic option as an add-on treatment for severe refractory eosinophilic asthma limited to certain patients (see Chapter 09 Role in the care pathway).

◗ **Public health impact**:

Considering:

– the seriousness of severe asthma,

– its prevalence,

– the partially met medical need in adult patients with severe refractory eosinophilic asthma,

– the lack of additional response to the identified need due to:

- the absence of an expected additional impact on morbidity and mortality;
- the absence of demonstration of a potential impact on the organisation of care;

NUCALA (mepolizumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NUCALA (mepolizumab) is substantial only as an add-on treatment for severe refractory eosinophilic asthma in adults meeting the following criteria:

– **a blood eosinophil count of ≥ 150/µL within the past 12 months;**

AND

- **at least two episodes of asthma exacerbations having required oral corticosteroid therapy (≥ 3 days each) in the past 12 months despite maintenance therapy combining high-dose inhaled corticosteroids and a long-acting bronchodilator (LABA);**
- **OR oral corticosteroid therapy for at least 6 months in the past 12 months.**

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.

The clinical benefit of NUCALA (mepolizumab) is insufficient in other clinical situations to justify public funding cover.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use

in the MA indication in adults meeting the criteria defined above, for whom the clinical benefit is substantial.

The Committee issues an unfavourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in other clinical situations.

Recommended reimbursement rate: 65%