

Nucala® (mepolizumab)

When requesting Nucala® (mepolizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Nucala is indicated for the:

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis

Coverage Guidelines

Severe Asthma with an Eosinophilic Phenotype

Initial authorization:

The individual must meet **all** of the following criteria for approval:

- Has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy (e.g., Cinqair, Fasenra)
- Has received at least 3 consecutive months of following combination therapy:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND an anti-interleukin-5 therapy (e.g., Fasenra, Cinqair)

OR

- o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND at least one additional asthma controller/maintenance medication (e.g., inhaled long-acting beta₂ agonist (LABA) [e.g., Serevent Diskus]; inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; theophylline)

OR

- o A combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂ agonist (e.g., Symbicort, Advair, Dulera)
- Asthma is uncontrolled defined by ONE of the following:

- o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
- o Has experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
- o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
- o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
- o Asthma worsens upon tapering of oral corticosteroids therapy
- Is 6 years of age or older
- Nucala is prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Reauthorization:

The individual must meet **all** of the following for approval:

- Has already received at least 6 months of Nucala therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Nucala should be considered under initial criteria*)
- Continues to receive therapy with one inhaled corticosteroid (ICS) or on ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- Has responded to Nucala therapy (e.g., decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency room visits, or physician visits due to asthma; decreased requirement for oral corticosteroids therapy)

Eosinophilic Granulomatosis with Polyangiitis (EGPA) [Formerly known as Churg-Strauss Syndrome]

Initial authorization:

The individual must meet **all** of the following criteria for approval:

- Has tried a corticosteroid therapy (e.g., prednisone) for a minimum of 4 weeks
- Has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy (e.g., Cinqair, Fasenra)
- Is 18 years of age or older
- Nucala is prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist

Reauthorization:

The individual must meet **all** of the following criteria for approval:

- Has already received at least 6 months of Nucala therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Nucala should be considered under initial criteria*)
- Has responded to Nucala therapy (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels)

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Guidelines

Severe Asthma

Adults and adolescents aged 12 years and older:

The recommended dose of Nucala is 100 mg administered once every 4 weeks by subcutaneous injection.

Pediatric patients aged 6 to 11 years:

The recommended dose of Nucala is 40 mg administered once every 4 weeks by subcutaneous injection.

Eosinophilic Granulomatosis with Polyangiitis

The recommended dose of Nucala is 300 mg administered once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections.

References

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