

Nucala® (mepolizumab)

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

FDA-approved indication

- Nucala® (mepolizumab) is indicated for:
 - Add-on maintenance treatment of individuals with severe asthma having an eosinophilic phenotype
 - The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Approved Off-label Compendial use

- None

Coverage Guidelines

Asthma

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 6 years of age or older
- Nucala must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Patient has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks
- Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND
 - o At least ONE of the following:
 - Inhaled long-acting beta agonist (LABA) [e.g., Serevent Diskus]; OR
 - Inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; OR
 - Leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; OR
 - Theophylline
 - NOTE: Use of a combination inhaler containing both ICS and a LABA would fulfill the requirement.

- **EXCEPTION** to the requirement for a trial to one additional asthma controller/maintenance medication is if the patient already has been receiving anti-IL-5 therapy (e.g. Fasenra and Cinqair) in combination with an ICS for at least 3 consecutive months.
- Patient's asthma is uncontrolled defined by ONE of the following:
 - o The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o The patient experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
 - o Patient has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Patient has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o The patient's asthma worsens upon tapering of oral corticosteroids therapy

Approval duration: 6 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 6 months of therapy with Nucala (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)
- Patient continues to receive therapy with one inhaled corticosteroid (ICS) or on ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- The patient has responded to Nucala therapy as determined by the prescribing physician (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)

Approval duration: 12 months

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

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 18 years of age or older
- Nucala must be prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist
- Patient has tried therapy with a corticosteroid (e.g., prednisone) for a minimum of 4 weeks

- Patient has/had a blood eosinophil level of greater than or equal to 150 cells per microliter within the previous 6 weeks

Approval duration: 6 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 6 months of therapy with Nucala (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)
- The patient has responded to Nucala therapy as determined by the prescribing physician (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels)

Approval duration: 12 months

Dosing Guidelines

Asthma:

- For pediatric patients (6 to 11 years of age): The dose is 40 mg administered subcutaneously once every 4 weeks.
- For patients ≥ 12 years of age: The dose is 100 mg administered subcutaneously once every 4 weeks.

EGPA: The dose is 300 mg injected subcutaneously once every 4 weeks.

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