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 with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis.
- Treatment of hypereosinophilic syndrome (HES) in patients aged 12 years and older who have had HES for greater than or equal to 6 months without an identifiable non-hematologic secondary cause.

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 the following combination therapy:
  - 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
  - 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
  - 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; AND
• 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); AND
• 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 0

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; AND
• 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**); AND
• Has responded to Nucala therapy (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels).
Hypereosinophilic Syndrome (HES)

**Initial authorization:**
The individual must meet **all** of the following criteria for approval:
- Has had hypereosinophilic syndrome for greater than or equal to 6 months;
- Has FIP1L1-PDGFRα-negative disease;
- Does NOT have an identifiable non-hematologic secondary cause of HES (e.g., drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy);
- Has/had a blood eosinophil level of greater than or equal to 1,000 cells per microliter prior to treatment with any anti-interleukin-5 therapy (e.g., Cinqair, Fasenra);
- Has tried at least one other treatment for HES (e.g., systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, methotrexate, tacrolimus, azathioprine) for a minimum of 4 weeks;
- Is 12 years of age or older; AND
- 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 8 months of Nucala therapy *(NOTE: Patients who have received less than 8 months of therapy or those who are restarting therapy with Nucala should be considered under initial criteria)*; AND
- Has responded to Nucala therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroid requirements, decreased eosinophil levels).

**Approval duration:**
- Initial authorization: Hypereosinophilic syndrome 8 months, other indications 6 months
- Reauthorization: 12 months

**Dosing Guidelines**

**Severe Asthma**
Adults and adolescents aged 12 years and older:
Approve 100 mg administered once every 4 weeks by subcutaneous injection.

Pediatric patients aged 6 to 11 years:
Approve 40 mg administered once every 4 weeks by subcutaneous injection.

**Eosinophilic Granulomatosis with Polyangiitis; Hypereosinophilic Syndrome**
Approve 300 mg administered once every 4 weeks by subcutaneous injection as 3 separate 100-mg injections.
References