

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 adults and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis.
- Treatment of adults and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for at least 6 months without an identifiable non-hematologic secondary cause.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults patients 18 years of age and older with inadequate response to nasal corticosteroids.

Coverage Guidelines

Severe Asthma

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 Nucala or another monoclonal antibody therapy that may lower blood eosinophil levels (i.e., Cinqair, Dupixent, Fasenra, Tezspire, Xolair);
- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);
- Asthma is/was uncontrolled prior to starting Nucala or another monoclonal antibody therapy (e.g., Fasenra, Dupixent, Cinqair, Tezspire, Xolair) defined by ONE of the following:
 - Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - Has experienced one or more asthma exacerbations requiring hospitalization, emergency room visits, or urgent care visits in the previous year; OR
 - Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - 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 one 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, urgent care visits, or medical clinic 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 active, non-severe disease defined as vasculitis without life- or organ-threatening manifestations (examples of symptoms of non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis);
- 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 monoclonal antibody therapy that may lower blood eosinophil levels (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.
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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, reduced corticosteroid dose, 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-PDGFR α -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 monoclonal antibody therapy that may lower blood eosinophil levels (e.g., Cinqair, Fasenra);
- Has tried at least one other treatment for HES (e.g., systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, pegylated-interferon) for a minimum of 4 weeks;
- Is 12 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 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*);
- Has responded to Nucala therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroid requirements, decreased eosinophil levels).

Nasal Polyps

Initial authorization:

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

- Has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan;
- Has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell;
- Has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive an intranasal corticosteroid concomitantly with Nucala;
- Meets ONE of the following:
 - Has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
 - Has a contraindication to systemic corticosteroid therapy; OR
 - Has had prior surgery for nasal polyps;
- Is 18 years of age or older;
- Nucala is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist)

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*);
- Continues to receive an intranasal corticosteroid therapy;
- Has responded to Nucala therapy (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell)

Approval duration:

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

Dosing Recommendations

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; Hypereosinophilic Syndrome

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

Chronic Rhinosinusitis with Nasal Polyps

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

References

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