



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.
- Add-on maintenance treatment of patients 18 years and older with chronic rhinosinusitis with nasal polyps

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:
 - 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; 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 active, non-severe disease (non-severe disease- vasculitis without life- or organ-threatening manifestations. Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis.); AND
- 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-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 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).

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; AND
- 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; AND
- Has received at least 3 months of therapy with an intranasal corticosteroid and will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala
- Meets ONE of the following:
 - o has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
 - o has a contraindication to systemic corticosteroid therapy; OR
 - o has had prior surgery for nasal polyps; AND
- Is 18 years of age or older; AND
- 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); AND
- Continues to receive therapy with an intranasal corticosteroid; AND
- 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 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.

Nasal Polyps

100 mg administered once every 4 weeks by subcutaneous injection.

References

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