

Nucala® (mepolizumab)

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

FDA-Approved Indications

Nucala is an interleukin-5 (IL-5) antagonist monoclonal antibody indicated for:

- Add-on maintenance treatment of adults and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis.
- The 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 adult patients aged 18 years and older with chronic rhinosinusitis with nasal polyps.
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Coverage Guidelines

Severe Asthma

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

- Has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Cinqair, Dupixent, Adbry, Ebglyss, Nemluvio, 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, 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:
 - 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 exacerbation(s) requiring hospitalization, emergency room visits, or urgent care visits 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 corticosteroid therapy;
- Is 6 years of age or older;
- Nucala is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- 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).

Chronic Obstructive Pulmonary Disease (COPD)

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

- Is 18 years of age or older;
- Has a blood eosinophil count of greater than or equal to 300 cells per microliter within the previous 6 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Cinqair, Dupixent, Adbry, Ebglyss, Nemluvio, Fasenra, Tezspire, Xolair);
- Meets one of the following:
 - o Has received at least 3 consecutive months of combination therapy with all of the following: inhaled long-acting beta₂-agonist (LABA), inhaled long-acting muscarinic antagonist (LAMA), and inhaled corticosteroid (ICS); OR
 - o Has received at least 3 consecutive months of combination therapy with an inhaled LABA and an inhaled LAMA and has a contraindication to the use of an inhaled corticosteroid;
- Meets one of the following:
 - o Has experienced two or more COPD exacerbations requiring treatment with a systemic corticosteroid with or without an antibiotic in the previous 12 months; OR
 - o Has experienced one or more COPD exacerbation(s) requiring a hospitalization in the previous 12 months (*Note: A hospitalization includes a hospital admission or an emergency medical care visit with observation lasting > 24 hours*);
- Nucala is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

The individual must meet all of the following criteria for re-authorization:

- Has already received at least 6 months of Nucala therapy (*NOTE: Patients who have received < 6 months of therapy or those who are restarting therapy with Nucala should be considered under initial criteria*);
- Continues to receive combination therapy with an inhaled LABA and LAMA;
- Has experienced a beneficial clinical response defined by one of the following:
 - o Reduced COPD symptoms; OR
 - o Reduced COPD exacerbations; OR
 - o Reduced COPD-related hospitalizations; OR
 - o Reduced emergency department or urgent care visit; OR
 - o Improved lung function parameters.

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

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

- 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);
- Is currently receiving a systemic corticosteroid (e.g., prednisone) and has been on therapy 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 4 weeks or prior to treatment with Nucala or another monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Cinqair, Dupixent, Adbry, Ebglyss, Nemluvio, Fasenra, Tezspire, Xolair);
- Is 18 years of age or older;
- Nucala is prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist.

The individual must meet both of the following criteria for re-authorization:

- Has already received at least 9 months of Nucala therapy (*NOTE: Patients who have received less than 9 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)

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

- Has had hypereosinophilic syndrome for at least 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 alter blood eosinophil levels (e.g., Cinqair, Dupixent, Adbry, Ebglyss, Nemluvio, Fasenra, Tezspire, Xolair);
- 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.

The individual must meet both of the following criteria for re-authorization:

- 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).

Chronic Rhinosinusitis with Nasal Polyps

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

- Has chronic rhinosinusitis with nasal polyps 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 4 weeks 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).

The individual must meet all of the following criteria for re-authorization:

- 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: HES 8 months; EGPA 9 months; other indications 6 months

Reauthorization: 12 months

Dosing Recommendations

Severe Asthma**Adults and adolescents aged 12 years and older:**

The recommended dose is 100 mg administered subcutaneously once every 4 weeks.

Pediatric patients aged 6 to 11 years:

The recommended dose is 40 mg administered subcutaneously once every 4 weeks.

Eosinophilic Granulomatosis with Polyangiitis and Hypereosinophilic Syndrome

The recommended dose is 300 mg administered subcutaneously once every 4 weeks.

Chronic Rhinosinusitis with Nasal Polyps and Chronic Obstructive Pulmonary Disease

The recommended dose is 100 mg administered subcutaneously once every 4 weeks.

References

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