Applicable Drugs: Nucala (mepolizumab)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/5/2016

Date Last Reviewed / Revised: 5/12/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and IV are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

A. Severe asthma with an eosinophilic phenotype

1. Documented blood eosinophilia count of at least 150 cells/mcL at baseline.
2. Documentation that the patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid (ICS) used in combination with a long-acting inhaled beta-2 agonist (LABA).
3. Documentation that the patient's asthma symptoms are poorly controlled despite therapy AND meets at least one of the following criteria:
   a) Poor symptom control (eg, Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20).
   b) Two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.
   c) One or more asthma exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, or emergency room visit) within the past 12 months.
   d) Worsening asthma when oral corticosteroids are tapered.
   e) Baseline forced expiratory volume in one second (FEV1) less than 80% predicted.
4. Documentation that Nucala will be used in conjunction with ICS + LABA therapy as an add-on maintenance treatment.
5. Minimum age requirement: 6 years old.

B. Chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype

1. Documented spirometry test meeting both of the following criteria:
   a) Post-bronchodilator FEV1/FVC less than 0.7.
   b) Post-bronchodilator FEV1 between 30% to 70% predicted normal.

2. Documented blood eosinophil count of at least 300 cells/mcL at baseline.
3. Documentation that the patient has been on a minimum of a six-month trial on LAMA + LABA + ICS (long-acting muscarinic antagonist + long-acting beta agonist + inhaled corticosteroids) therapy OR LAMA + LABA therapy if ICS is contraindicated.
4. Documentation of COPD exacerbation history in the past 12 months that meets one of the following criteria (a or b):
    a) Two or more COPD exacerbations requiring systemic corticosteroids and/or antibiotics. One of the exacerbations must require the use of systemic corticosteroids.
    b) One or more COPD exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, or emergency room visit).
5. Documentation that Nucala will be used in conjunction with LAMA + LABA + ICS or LAMA + LABA therapy as an add-on maintenance treatment.
6. Minimum age requirement: 18 years old.

C. Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Documentation that the patient has had two or more of the following signs and symptoms for at least 12 weeks:
    a) Facial pain, pressure, or fullness
    b) Nasal blockage, obstruction, or congestion
    c) Purulent drainage
    d) Reduced or absent sense of smell
2. Documented presence of nasal polyps by one of the following:
    a) Sinus CT
    b) Nasal endoscopy
    c) Anterior rhinoscopy
    d) Sinus MRI
3. Documented treatment failure, intolerance, or contraindication to an intranasal corticosteroid used for a minimum of 4 weeks.
4. Documented treatment failure, intolerance, or contraindication to an oral corticosteroid to reduce size of nasal polyps OR had a polypectomy.
5. Documentation that Nucala will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
6. Minimum age requirement: 18 years old.

D. Eosinophilic granulomatosis with polyangiitis (EGPA, formerly Churg-Strauss Syndrome)

1. Documentation of active, non-severe disease as defined as vasculitis without life- or-organ-threatening manifestations (eg, rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis).
2. Documentation of one of the following criteria (a or b):
    a) Blood eosinophil count of at least 1000 cells/mcL.
    b) Blood eosinophil level of at least 10%.
3. Documented history or presence of asthma
4. Documentation of at least two of the following disease characteristics:
    a) Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    b) Neuropathy
    c) Non-fixed pulmonary infiltrates
    d) Sinonasal abnormality
    e) Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    f) Glomerulonephritis (hematuria, red cell casts, and proteinuria)
    g) Alveolar hemorrhage
    h) Palpable purpura
    i) Anti-neutrophil cytoplasmic antibody (ANCA) positivity
5. Documentation that the patient is stable on an oral corticosteroid at dose 7.5 mg to 50 mg of prednisone or prednisolone per day or equivalent for at least 4 weeks or has a contraindication to corticosteroid therapy.
6. Documented treatment failure to one or contraindication to all systemic immunosuppressant(s) (ie, azathioprine, cyclophosphamide, methotrexate, or mycophenolate mofetil) for at least 4 weeks.
7. Documentation that Nucala will be used in conjunction with an oral corticosteroid as an add-on maintenance treatment.
8. Minimum age requirement: 18 years old.

E. Hypereosinophilic syndrome (HES)

1. Documentation of active, non-severe HES diagnosis for at least 6 months.
2. Documentation of both of the following criteria:
    a) HES is not secondary to a non-hematologic cause (ie, drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy).

b) HES is not Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-positive.

3. Documentation of at least 2 HES flares (eg, worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy) within the past 12 months.
4. Documentation of a blood eosinophil count of at least 1,000 cells/mcL.
5. Documentation that the patient is stable on HES therapy (ie, oral corticosteroids, cytotoxic, or immunosuppressive therapy [ie, azathioprine, chlorambucil, imatinib, pegylated-interferon, vincristine, etc.]) for at least 4 weeks.
6. Documentation that Nucala will be used in conjunction with background HES therapy as an add-on maintenance treatment.
7. Minimum age requirement: 12 years old.

II. Treatment must be prescribed by or in consultation with an allergist, immunologist, cardiologist, hematologist, otolaryngologist, pulmonologist, or rheumatologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of acute bronchospasm or status asthmaticus.
- Concurrent use with other anti-asthma monoclonal antibodies (ie, Cinqair [reslizumab], Dupixent [dupilumab], Exdensur [depemokimab], Fasenra [benralizumab], Tezspire [tezepelumab], Xolair [omalizumab]).
- Concurrent use with other anti-COPD agents (ie, Dupixent [dupilumab] and Ohtuvayre [ensifentrine]).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Asthma:
  - Age 6 to 11 years old: One 40 mg prefilled syringe every 28 days.
  - Age 12 years and older: One 100 mg vial, autoinjector, or prefilled syringe every 28 days.

- COPD: One 100 mg vial, autoinjector, or prefilled syringe every 28 days.
- CRSwNP: One 100 mg vial, autoinjector, or prefilled syringe every 28 days.
- EGPA: Three 100 mg vials, autoinjectors, or prefilled syringes every 28 days.
- HES: Three 100 mg vials, autoinjectors, or prefilled syringes every 28 days.

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months, with an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

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3. Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. 2026. https://goldcopd.org/wp-content/uploads/2026/01/GOLD-REPORT-2026-v1.3-8Dec2025_WMV2.pdf
4. Payne SC, McKenna M, Buckley J, et al. Clinical Practice Guideline: Adult Sinusitis Update. Otolaryngol Head Neck Surg. 2025;173 Suppl 1:S1-S56. doi:10.1002/ohn.1344
5. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med.* 2017;376(20):1921-1932. doi:10.1056/NEJMoa1702079
6. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis Care Res (Hoboken)*. 2021;73(8):1088-1105. doi:10.1002/acr.24634
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8. Shomali W, Gotlib J. World Health Organization and International Consensus Classification of eosinophilic disorders: 2024 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2024;99(5):946-968. doi:10.1002/ajh.27287

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.