Generic Name: Mepolizumab

Therapeutic Class or Brand Name: Nucala

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/5/2016

Date Last Reviewed / Revised: 5/29/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I and III 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 ≥ 150 cells/mcL at baseline.
2. Documentation that the patient has been on a minimum of a 6-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 through e:
   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, 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) < 80% predicted.
4. Treatment must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
5. Minimum age requirement: 6 years old.

B. Moderate-to-severe chronic obstructive pulmonary disease (COPD)

1. Documentation of both a and b:
   a) Spirometry test confirming COPD diagnosis, meeting criteria i and ii:
      i. Post-bronchodilator FEV1/FVC less than 0.7.

ii. Post-bronchodilator FEV1 30 to 70% predicted normal.

b) Blood eosinophil count of at least 300 cells/microliter at baseline.

2. Documentation of history of chronic bronchitis.
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 criteria a OR b:
   a) Two or more COPD exacerbations requiring systemic corticosteroids and/or antibiotics.
      i. 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 2 the following signs/symptoms for 12 weeks or longer:
   a) Facial pain, pressure, or fullness
   b) Nasal blockage, obstruction, or congestion
   c) Purulent drainage
   d) Reduced or absent sense of smell
2. Documentation nasal polyps are present by one of the following:
   a) Sinus CT
   b) Nasal endoscopy
   c) Sinus MRI
3. Documentation patient's symptoms are inadequately controlled with a high-dose intranasal corticosteroid used for a minimum of 4 weeks.
4. Nucala will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
5. Documentation of treatment with oral corticosteroids to reduce size of nasal polyps OR history of polypectomy.

6. Treatment must be prescribed by or in consultation with an allergist, immunologist, otolaryngologist, or pulmonologist.
7. Minimum age requirement: 18 years old.

D. Eosinophilic granulomatosis with polyangiitis (EGPA)

1. Documentation of active, non-severe disease (vasculitis without life- or- organ-threatening manifestations (eg, rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis)).
2. Documentation of blood eosinophils ≥ 1500 cells/mL and/or ≥ 10% of leukocytes
3. Documented history or presence of asthma and at least two of the following disease characteristics a through i:
    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
4. Documentation that the patient is stable on daily corticosteroid therapy or has a contraindication to corticosteroid therapy.
5. Documented treatment failure to one or contraindication to all systemic immunosuppressant(s) (ie, azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil).
6. Treatment must be prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.
7. Minimum age requirement: 18 years old.

E. Hypereosinophilic syndrome (HES)

1. Documentation of active, non-severe HES diagnosis for ≥ 6 months
2. Documentation that HES is not:
    a) Secondary to a non-hematologic cause (ie, drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy).

b) Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-positive disease.

3. Documentation of at least 2 HES flares within the past 12 months.
4. Documentation of a blood eosinophil count of ≥ 1,000 cells/mcL.
5. Documentation that the patient meets the following criteria a and b:
   a) Treatment on a stable HES therapy for a minimum of 4 weeks (ie, oral corticosteroids, cytotoxic, or immunosuppressive therapy (ie, azathioprine, chlorambucil, imatinib, pegylated-interferon, vincristine, etc.).
   b) Nucala will not be used as monotherapy.
6. Treatment must be prescribed by or in consultation with an allergist, immunologist, cardiologist, hematologist, or pulmonologist.
7. Minimum age requirement: 12 years old.

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

III. 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 other eosinophilic conditions.
- Treatment of acute bronchospasm or status asthmaticus.
- Treatment of active, severe EGPA (eg, vasculitis with life-or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia).
- Treatment of non-hematologic secondary HES (eg, drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRa kinase-positive HES.
- Concurrent use with other anti-asthma monoclonal antibodies (ie, Cinqair (reslizumab), Dupixent (dupilumab), Fasenra (benralizumab), Tezspire (tezepelumab), Xolair (omalizumab)).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Severe eosinophilic 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

1. Nucala. Prescribing information. GlaxoSmithKline; 2023. Accessed June 20, 2024. https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL.PDF.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma [published correction appears in *Eur Respir J*. 2014 Apr;43(4):1216. Dosage error in article text] [published correction appears in *Eur Respir J*. 2018 Jul 27;52(1):] [published correction appears in *Eur Respir J*. 2022 Jun 9;59(6):]. *Eur Respir J*. 2014;43(2):343-373. doi:10.1183/09031936.00202013
3. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescent and adult patients: diagnosis and management V4.0. August 2023. Accessed October 15, 2023. https://ginasthma.org/severeasthma/
4. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398. doi:10.1016/j.jaci.2022.10.026
5. 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
6. 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

7. Butt NM, Lambert J, Ali S, et al. Guideline for the investigation and management of eosinophilia. *Br J Haematol*. 2017;176(4):553-572. doi:10.1111/bjh.14488

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.