STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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Office of Pharmacy Services
Prior Authorization Criteria
Nucala® (mepolizumab)
Effective 9/24/2025

Prior Authorization Request Form

NUCALA is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Treatment of adult and pediatric patients ≥12 years of age with hypereosinophilic syndrome (HES) for ≥ six months without an identifiable nonhematologic secondary cause.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with an inadequate response to nasal corticosteroids.
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Prior authorization requests for Nucala may be approved if the following criteria are met:

TREATMENT OF EOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
2. The patient must be within the age range as recommended by the Food and Drug Administration (FDA) label and indication; **AND**
3. Patient must have documented adherence to a therapeutic regimen consisting of a long-acting beta-agonist (LABA) + high dose inhaled corticosteroid (ICS) therapy in the last 90 days; **AND**
4. Documentation must be supplied indicating **one** of the following:
    a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3%; **OR**
    b. Asthma with eosinophilic phenotype with blood eosinophil counts greater than or equal to 150 cells/mcL within the past six weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
    c. Claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Nucala for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

TREATMENT OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA):

1. The patient must have a documented diagnosis of EGPA (also known as Churg-Strauss Syndrome) with the patient meeting at least four of the following diagnostic criteria:
    a. Asthma
    b. Eosinophilia of > 10% in peripheral blood
    c. Paranasal sinusitis
    d. Pulmonary infiltrates, sometimes transient
    e. Histologic evidence of vasculitis with extravascular eosinophils
    f. Multiple mononeuropathy or polyneuropathy, **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. The patient has failed to achieve remission of symptoms following at least a 90-day course of systemic glucocorticoid therapy equivalent to (or greater than) 7.5 mg/day of oral prednisone PLUS immunosuppressive therapy such as, but not restricted to, cyclophosphamide, methotrexate or azathioprine (unless contraindicated)*

* If the provider feels that immunosuppressive therapy is contraindicated, they must document the reason for this.

Initial approval of Nucala for EGPA will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

TREATMENT OF HYPEREOSINOPHILIC ASTHMA (HES):

1. Must be prescribed by or in consultation with an allergist, immunologist, hematologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. The patient must have a blood eosinophil count of ≥ 1,000 cells per mcL; **AND**

4. The patient has had at least two HES flares within the past 12 months; **AND**

5. The patient is on a stable dose of background HES therapy (chronic or episodic corticosteroids, immunosuppressive, or cytotoxic therapy) for at least four weeks prior to treatment initiation.

Initial approval of Nucala for HES will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

TREATMENT OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

1. Must be prescribed by or in consultation with an otolaryngologist, allergist, or other suitable specialist; **AND**

2. The patient must have a diagnosis of chronic rhinosinusitis with nasal polyps that have been inadequately controlled after at least three months of therapy with any intranasal steroid; **AND**

3. The patient must be within the approved age range according to the FDA label and indication; **AND**

4. Nucala is only approvable as add-on therapy for CRSwNP.

Initial approval of Nucala for CRSwNP will be for 90 days. Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Nucala was supplementing).

TREATMENT COPD WITH AN EOSINOPHILIC PHENOTYPE:

1. Prescribed by, or in consultation with, an M.D./D.O. pulmonologist or an allergist/immunologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. The patient must have an eosinophilic count of ≥ 150 cells per mcL within 12 months prior to initiation of therapy; **AND**

4. The patient has a history of uncontrolled disease, as indicated by ≥ two moderate* or ≥ one severe exacerbation* within the past 12 months; **AND**

5. The patient has been on standard of care triple therapy with at least one (1) inhaled long-acting anticholinergic (LAMA), at least one (1) inhaled long-acting beta-agonist (LABA), AND one (1) inhaled corticosteroid (ICS) for at least three months prior to request, and at a stable dose for at least 1 month prior. *LAMA-LABA is allowed if ICS is contraindicated.

*Moderate exacerbations are defined as exacerbations that resulted in treatment with a systemic corticosteroid, an antibiotic agent, or both. Severe exacerbations are defined as exacerbations that led to hospitalization or an emergency medical care visit. At least one of the moderate exacerbations was to have resulted in the use of systemic corticosteroid, and at least one exacerbation had to have occurred while the patient was receiving inhaled corticosteroid plus LAMA–LABA (or LAMA–LABA alone if inhaled corticosteroid was contraindicated).

Initial approval of Nucala for COPD will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on therapy.