

**Montana Healthcare Programs  
Physician Administered Drug Coverage Criteria  
NUCALA® (mepolizumab)**

**I. Medication Description**

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

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older and with an eosinophilic phenotype.
- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.

**II. Position Statement**

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

**III. Initial Coverage Criteria**

**Severe Eosinophilic Asthma:**

Member must meet all the following criteria:

- Member must be 6 years of age or older.
- Diagnosis of severe uncontrolled asthma with an eosinophilic phenotype.
- Must be prescribed by or in consult with an appropriate specialist (allergist/pulmonologist/immunologist).
- Must provide baseline peripheral blood eosinophil count (attach lab report with eosinophil count).
  - Criteria: ≥150 cells/microliter (past 6 weeks) or ≥300 cells/microliter (past year).
- Member has a history of *severe* asthma attacks despite treatment with inhaled corticosteroid (ICS) in combination with long-acting beta<sub>2</sub>-agonist (LABA) inhaler at optimized doses for 3 consecutive months.
- Provider attests member will not use Nucala® concomitantly with other biologics (e.g., Fasenra®, Dupixent®, Cinqair®, Xolair®).

**Eosinophilic Granulomatosis with Polyangitis (EGPA):**

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA).
- Must be prescribed by or in consult with an appropriate specialist (rheumatologist/pulmonologist/immunologist).
- Member is experiencing exacerbations while on stable dose of oral corticosteroids or during steroid taper.
- Immunosuppressive therapy has been ineffective, contraindicated or not tolerated.

**Hypereosinophilic Syndrome (HES):**

Member must meet all the following criteria:

- Member must be 12 years of age or older.
- Diagnosis of hypereosinophilic syndrome for  $\geq 6$  months.
- Must be prescribed by or in consult with an appropriate specialist (allergist/immunologist/pulmonologist/neurologist/cardiologist/dermatologist).

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (*Interim criteria until Board review*):**

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Must be prescribed by or in consult with an appropriate specialist (allergist/immunologist/otolaryngologist).
- Member has clinical documentation of chronic rhinosinusitis WITH nasal polyps, as evidenced by CT scan or endoscopy.
- Member must concurrently be using an intranasal corticosteroid, unless contraindicated.
- Member must have had an inadequate treatment response, intolerance or contraindication to BOTH of the following:
  - One different intranasal corticosteroids (must have been adherent to therapy at optimized doses for at least three months).
  - Systemic corticosteroid trial (must be within last year) *and/or* sino-nasal surgery.

**IV. Renewal Coverage Criteria****Severe Eosinophilic Asthma:**

Member must meet all the following criteria:

- Member has been adherent to Nucala® and ICS/LABA therapy.
- Member has experienced a positive clinical response (reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction).
- Annual specialist consult provided if prescriber is not a specialist.

**Eosinophilic Granulomatosis with Polyangitis (EGPA) and Hypereosinophilic Syndrome (HES):**

Member must meet all the following criteria:

- Member has been adherent to Nucala®.

- Member has experienced a positive clinical response (reduction in frequency and/or severity of symptoms and exacerbations or medication dose reduction).
- Annual specialist consult provided if prescriber is not a specialist.

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP):**

Member must meet all the following criteria:

- Member has been adherent to Nucala®.
- Member has been adherent to intranasal corticosteroid.
- Member has experienced a positive clinical response (reduction in polyp size, time to first nasal polypectomy, change in loss of smell, systemic steroid use).
- Annual specialist consult provided if prescriber is not a specialist.

**V. Quantity Limitations**

**Severe Eosinophilic Asthma:**

- 6 to 11 years: Max 40mg SQ every 4 weeks
- 12 years and older: Max 100mg SQ every 4 weeks

**EGPA:** Max 300mg SQ every 4 weeks

**HES:** Max 300mg SQ every 4 weeks

**CRSwNP:** Max 100mg SQ every 4 weeks

**VI. Coverage Duration**

**Severe Eosinophilic Asthma/EGPA/HES:**

- Initial approval duration: 6 months
- Renewal approval duration: 1 year

**CRSwNP:**

- Initial approval duration: 1 year
- Renewal approval duration: 1 year