

Montana Healthcare Programs  
Physician Administered Drug Coverage Criteria  
**NUCALA<sup>®</sup> (mepolizumab)**

**I. Medication Description**

Nucala<sup>®</sup> 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.
- 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.
- Prescriber must be specialist or have an annual consult on file (Pulmonology/Allergy/Immunology).
- 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 that member will not use Nucala<sup>®</sup> concomitantly with other biologics (e.g. Fasenra<sup>®</sup>, Dupixent<sup>®</sup>, Cinqair<sup>®</sup>, Xolair<sup>®</sup>).

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

Member must meet all the following criteria:

- Member must be 18 years of age or older.
- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA).
- Prescriber must be specialist or have an annual consult on file (Rheumatology/Pulmonology/Immunology).
- 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 ≥6 months.

- Prescriber must be a specialist (Allergy/Immunology/Pulmonology/Neurology/Cardiology/Dermatology) or have an annual consult on file.

#### **IV. Renewal Coverage Criteria**

Member must meet all the following criteria:

- Member has been adherent to Nucala® (and ICS/LABA therapy for eosinophilic asthma).
- 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 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

#### **VI. Coverage Duration**

Initial approval duration: 6 months

Renewal approval duration: 1 year