

# SPECIALTY GUIDELINE MANAGEMENT

## NUCALA (mepolizumab)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

##### 1. Maintenance Treatment of Severe Asthma

Nucala is an interleukin-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.

*Limitations of Use:* Not for relief of acute bronchospasm or status asthmaticus

##### 2. Eosinophilic Granulomatosis with Polyangiitis

Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

All other indications are considered experimental/investigational and are not a covered benefit.

#### II. CRITERIA FOR INITIAL APPROVAL

##### A. Eosinophilic asthma

Authorization of 12 months may be granted for treatment of eosinophilic asthma when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
3. Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses:
  - a. Inhaled corticosteroid
  - b. Additional controller (long acting beta<sub>2</sub>-agonist, leukotriene modifier, or sustained-release theophylline)

##### B. Eosinophilic Granulomatosis with Polyangiitis

Authorization of 12 months may be granted for treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.

#### III. CONTINUATION OF THERAPY

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**A. Eosinophilic asthma**

Authorization of 12 months may be granted for continuation of treatment of eosinophilic asthma when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Asthma control has improved on Nucala treatment as demonstrated by either:
  - a. A reduction in the frequency or severity of symptoms and exacerbations, or
  - b. A reduction in the daily maintenance oral corticosteroid dose

**B. Eosinophilic Granulomatosis with Polyangiitis**

Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has beneficial response to treatment with Nucala as demonstrated by any of the following:
  - a. A reduction in the frequency of relapses, or
  - b. A reduction in the daily oral corticosteroid dose, or
  - c. No active vasculitis

**IV. REFERENCES**

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4. National Institutes of Health. *National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007*. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>. Accessed March 2, 2017.
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7. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med*. 2017;18;376(20):1921-1932.