CareFirst Family of health care plans

CVS caremark™

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. Severe asthma with an eosinophilic phenotype
Authorization of 12 months may be granted for treatment of severe asthma with an eosinophilic phenotype when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member has a baseline 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.
   1. Inhaled corticosteroid
   2. Additional controller (long acting $beta_2$-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

A. Severe asthma with an eosinophilic phenotype

Authorization of 12 months may be granted for continuation of treatment of severe asthma with an eosinophilic phenotype 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.