Effective Date: 12/2017
Revised: 12/2018, 12/2019 Reviewed: 12/2017, 12/2018, 12/2019 Scope: Medicaid

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

A. Nucala is indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
B. Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

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

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (initial requests only):

A. Asthma:
   1. Initial requests: documentation of baseline blood eosinophil count and components of severity that classify asthma as severe
   2. Continuation of therapy requests: documentation of improved asthma control
B. EGPA:
   1. Initial requests: documentation of baseline blood eosinophil count or level as noted in section III.B.4. below
   2. Continuation of therapy requests: documentation of beneficial response to treatment

III. CRITERIA FOR INITIAL APPROVAL

A. Asthma

Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Nucala is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
3. Member has severe asthma (see Appendix).
4. Member has a baseline blood eosinophil count of at least 150 cells per microliter.

5. Member is adherent to current treatment with both of the following medications at optimized doses:
   a. Inhaled corticosteroid
   b. Additional controller medication (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
5. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations)
6. Member will use Nucala as add-on maintenance treatment.
7. Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair).

B. Eosinophilic granulomatosis with polyangiitis

Authorization of 6 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. Nucala is prescribed by, or in consultation with, a pulmonologist, rheumatologist or allergist/immunologist.
3. Member has history or presence of asthma.
4. 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%
5. Member has at least two of the following disease characteristics of EGPA:
   a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   c. Pulmonary infiltrates, non-fixed; sino-nasal abnormality
   d. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   e. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   f. Alveolar hemorrhage (by bronchoalveolar lavage)
   g. Palpable purpura
   h. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)
6. Member has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day)
7. Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease.

IV. CONTINUATION OF THERAPY

A. Asthma

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

1. Member is 6 years of age or older.
2. Nucala is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
3. Member is tolerating treatment.

4. Asthma control has improved/stabilized on Nucala treatment from baseline as demonstrated by at least one of the following:
   a. A reduction in the frequency and/or severity of symptoms and exacerbations (e.g. decrease in hospitalizations, emergency department or urgent care visits)
   b. A reduction in the daily maintenance oral corticosteroid dose
5. Member will use Nucala as add-on maintenance treatment.
6. Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair).

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. Nucala is prescribed by, or in consultation with, a pulmonologist, rheumatologist or allergist/immunologist.
3. Member is tolerating treatment.
4. 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

V. QUANTITY LIMIT

Nucala has a quantity limit of 3 vials/syringes/pens (300mg) per 28 days. For the diagnosis of asthma, the dose will be limited to 100 mg per 28 days.

VI. APPENDIX

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma