Effective Date: 12/2017
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SPECIALTY GUIDELINE MANAGEMENT

NUCALA (mepolizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendia 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).
C. Nucala is indicated for treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES).

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 within 6 weeks of dosing.
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 (EPGA)

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. Patient has a confirmed diagnosis of EGPA(See Appendix); AND
4. Member has a history or the presence of an eosinophil count of ≥ 150cells per microliter within 6 weeks of dosing
5. 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)
6. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses, etc.)

C. Hypereosinophilic syndrome (HES)

Authorization of 6 months may be granted for treatment of hypereosinophilic syndrome (HES) when all of the following criteria are met:

1. Patient is at least 12 years of age; **AND**
2. Patient has been diagnosed with HES for at least 6 months prior to starting treatment; **AND**
3. Patient does NOT have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRα kinase-positive HES; **AND**
4. Patient has a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
5. Patient must have blood eosinophils ≥1000 cells/μL within 4 weeks of dosing; **AND**

6. Used in combination with at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy, etc.)

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. Documentation of improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:
    (1) Use of systemic corticosteroids
    (2) Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    (3) Hospitalizations
    (4) ER visits
    (5) Unscheduled visits to healthcare provider; OR
5. Improvement from baseline in forced expiratory volume in 1 second (FEV_1)
6. Member will use Nucala as add-on maintenance treatment.
2. 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. Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in one or more of the following:
    a) Patient is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
    b) Decrease in maintenance dose of systemic corticosteroids
    c) Improvement in BVAS score compared to baseline
    d) Improvement in asthma symptoms or asthma exacerbations
    e) Improvement in duration of remission or decrease in the rate of relapses

C. Hypereosinophilic syndrome (HES)

Authorization of 12 months may be granted for continuation of treatment of hypereosinophilic syndrome when disease response is indicated by a decrease in HES flares from baseline (**Note:** An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy).

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 for adults and adolescents aged 12 years and older and 40mg per 28 days for pediatric Patients Aged 6 to 11 years.

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

Eosinophilic granulomatosis with polyangiitis defined as all of the following:

1. History or presence of asthma
2. Blood eosinophil level > 10% or an absolute eosinophil count >1000 cells/mm^3
3. Two or more of the following criteria:
    a. Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation
    b. Neuropathy
    c. Pulmonary infiltrates
    d. Sinonasal abnormalities
    e. Cardiomyopathy
    f. Glomerulonephritis
    g. Alveolar hemorrhage
    h. Palpable purpura
    i. Antineutrophil Cytoplasmic Antibody (ANCA) positivity