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).
D. Nucala is indicated for the add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

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. HES:
   1. Initial requests: documentation of baseline blood eosinophil count or level as noted in section III.C.5. below
   2. Continuation of therapy requests: documentation of beneficial response to treatment
C. 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
D. CRSwNP:
   1. Initial requests: documentation of previous therapies or surgeries and baseline disease severity

2. Continuation of therapy requests: documentation of beneficial response to treatment

III. CRITERIA FOR INITIAL APPROVAL

A. Severe Asthma

Authorization of 6 months may be granted for treatment of asthma when all 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 documentation of severe asthma (see Appendix).
4. Member has a baseline blood eosinophil count≥300 cells/μL within previous 12 months or ≥150 cells/μL within 6 weeks of dosing.
5. Member is adherent to current treatment with both of the following medications at optimized doses:
   a. Meduim-high doesed inhaled corticosteroids
   b. Additional controller medication (long acting beta$_2$-agonist, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated
6. Will not be used for treatment acute bronchospasm or status asthmaticus.
7. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., daily oral corticosteroids for at least 3 days, emergency department or urgent care visits, or hospitalizations) in addition to regular maintenance therapy defined above
8. Member will use Nucala as add-on maintenance treatment.
9. Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair).
10. Baseline measurement of at least one of the following for assessment of clinical status:
    a. Use of systemic corticosteroids
    b. Use of inhaled corticosteroids
    c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    d. Forced expiratory volume in 1 second (FEV_1)

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
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
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)
5. Patient must have blood eosinophils ≥1000 cells/μL within 4 weeks of dosing; AND
6. Used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy, etc.)

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Authorization of 6 months may be granted for treatment of Chronic Rhinosinusitis with Nasal Polyps when all of the following criteria are met:

1. Patient is at least 18 years of age
2. Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks
3. Patient has failed on at least 8 weeks of intranasal corticosteroid therapy;
4. Patient meets ONE of the following:
    a) Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years
    b) Patient has a contraindication to systemic corticosteroid therapy
    c) Patient has had prior surgery for nasal polyps
5. Patient does not have any of the following:
    a. Antrochoanal polyps
    b. Nasal septal deviation that would occlude at least one nostril
    c. Disease with lack of signs of type 2 inflammation
    d. Cystic fibrosis
    e. Mucoceles

6. Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.)
7. Physician has assessed baseline disease severity utilizing an objective measure/tool
8. Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated
9. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).

IV. CONTINUATION OF THERAPY

A. Severe 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].

D. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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

Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.].

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. For the diagnosis of CRSwNP, 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

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