Commercial/Healthcare Exchange PA Criteria

Effective: December 9, 2021

Prior Authorization: Nucala®

Products Affected: Nucala (mepolizumab subcutaneous injection)

Medication Description:

Mepolizumab is an interleukin-5 (IL-5) antagonist monoclonal antibody that reduces the production and survival of eosinophils by blocking the binding of IL-5 to the alpha chain of the receptor complex on the eosinophil cell surface.

Covered Uses:

1. **Asthma**, as add-on maintenance treatment of patients ≥ 6 years of age with severe disease and an eosinophilic phenotype. Limitations of Use: Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.
2. **Chronic rhinosinusitis with nasal polyposis** (CRSwnP), as an add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.
3. **Eosinophilic granulomatosis with polyangiitis** (EGPA) [formerly known as Churg-Strauss Syndrome] in adult patients.
4. **Hypereosinophilic syndrome** (HES) in patients ≥ 12 years of age who have had HES for ≥ 6 months without an identifiable non-hematologic secondary cause.

Exclusion Criteria:

Asthma - Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

Required Medical Information:

1. Diagnosis
2. Previous therapies tried

Age Restrictions:

Asthma- ≥ 6 years of age
Eosinophilic Granulomatosis with Polyangiitis- ≥ 18 years of age
Hypereosinophilic Syndrome- ≥ 12 years of age
Nasal Polyps- ≥ 18 years of age

Prescriber Restrictions:

Nucala is prescribed by or in consultation with an allergist, immunologist, otolaryngologist, pulmonologist, or rheumatologist.

Coverage Duration:

Asthma- Initial:6 months Continuation: 12 months
Eosinophilic Granulomatosis with Polyangiitis- Initial: 6 months Continuation: 12 months
Hypereosinophilic Syndrome- Initial: 8 months Continuation: 12 months
Nasal Polyps- Initial 6 months Continuation: 12 months

Other Criteria:

1. **Asthma.** Approve Nucala for the duration noted if the patient meets one of the following conditions (A **or** B):
   - **A.** Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, **and** v):
     - **i.** Patient is ≥ 6 years of age; **AND**
     - **ii.** Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy; **AND**
       Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair® (reslizumab intravenous injection), and Fasenra® (benralizumab subcutaneous injection).
     - **iii.** Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a **and** b):
       - **a.** An inhaled corticosteroid; **AND**
       - **b.** At least one additional asthma controller or asthma maintenance medication; **AND**

       Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, anti-interleukin-5 therapies (e.g., Cinqair, Fasenra, Nucala), and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta$_2$-agonist would fulfil the requirement for both criteria a and b.
     - **iv.** Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, **or** e):
       - **a.** Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
       - **b.** Patient experienced one or more asthma exacerbation(s) requiring hospitalization or an Emergency Department visit in the previous year; **OR**
       - **c.** Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**
       - **d.** Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **OR**
       - **e.** The patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**

         Note: "Baseline" is defined as prior to receiving any Nucala or other anti-interleukin-5 therapies (i.e., Fasenra or Nucala).
     - **v.** The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
   - **B.** Patient is Currently Receiving Nucala. Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):
     - **i.** Patient has already received at least 6 months of therapy with Nucala; **AND**
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Nucala should be considered under criterion 1A (Asthma, Initial Therapy).
     - **ii.** Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
     - **iii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Nucala therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department/urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

2. **Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome].** Approve Nucala for the duration noted if the patient meets one of the following conditions (A **or** B):
   - **A.** Initial Therapy. Approve for 6 months if the patient meets the following conditions (i, ii, iii, **and** iv):
     - **i.** Patient is ≥ 18 years of age; **AND**
     - **ii.** Patient has active, non-severe disease; **AND**
       Note: Non-severe disease is defined as vasculitis without life- or organ-threatening manifestations. Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis.
     - **iii.** Patient has/had a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy; **AND**
       Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair, and Fasenra.
     - **iv.** Patient has tried therapy with a corticosteroid (e.g., prednisone) for a minimum of 4 weeks; **AND**
     - **v.** The medication is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.
   - **B.** Patient is Currently Receiving Nucala. Approve for 1 year if the patient meets the following criteria (i **and** ii):
     - **i.** Patient has already received at least 6 months of therapy with Nucala; **AND**
       Note: A patient who has received < 6 months of therapy or who is restarting therapy with Nucala should be considered under criterion 2A (Eosinophilic Granulomatosis with Polyangiitis, Initial Therapy).
     - **ii.** Patient has responded to therapy as determined by the prescriber.
       Note: Examples of a response to Nucala therapy are reduced rate of relapse, corticosteroid dose reduction, and reduced eosinophil levels.

3. **Hypereosinophilic Syndrome.** Approve Nucala for the duration noted if the patient meets one of the following conditions (A **or** B):
   - **A.** Initial Therapy. Approve for 8 months if the patient meets the following conditions (i, ii, iii, iv, v, vi, **and** vii):
     - **i.** Patient is ≥ 12 years of age; **AND**;
     - **ii.** Patient has had hypereosinophilic syndrome for ≥ 6 months; **AND**
     - **iii.** Patient has FIP1L1-PDGFRα-negative disease; **AND**
     - **iv.** Patient does NOT have an identifiable non-hematologic secondary cause of hypereosinophilic syndrome according to the prescriber; **AND**
       Note: Examples of secondary causes of hypereosinophilic syndrome include drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy.
     - **v.** Patient has/had a blood eosinophil level ≥ 1,000 cells per microliter prior to treatment with any anti-interleukin-5 therapy; **AND**
       Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair, and Fasenra.
     - **vi.** Patient has tried at least one other treatment for hypereosinophilic syndrome for a minimum of 4 weeks; **AND**
       Note: Treatments for hypereosinophilic syndrome include systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, methotrexate, tacrolimus, and azathioprine.
     - **vii.** Nucala is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.
   - **B.** Patient is Currently Receiving Nucala. Approve for 1 year if the patient meets the following criteria (i **and** ii):
     - **i.** Patient has already received at least 8 months of therapy with Nucala; **AND**
       Note: A patient who has received < 8 months of therapy or who is restarting therapy with Nucala should be considered under criterion 3A (Hypereosinophilic Syndrome, Initial Therapy).

ii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Nucala therapy are decreased number of flares, improved fatigue, reduced corticosteroid requirements, and decreased eosinophil levels.

4. Nasal Polyps. Approve Nucala for the duration noted if the patient meets one of the following conditions (A **or** B):

A. Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, v, **and** vi):

i. Patient is ≥ 18 years of age; **AND**
ii. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed **tomography (**CT) scan; **AND**
iii. Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; **AND**
iv. Patient meets BOTH of the following (a **and** b):
   a. Patient has received at least 3 months of therapy with an intranasal corticosteroid; **AND**
   b. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Nucala; **AND**
v. Patient meets ONE of the following (a, b, **or** c):
   a. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; **OR**
   b. Patient has a contraindication to systemic corticosteroid therapy; **OR**
   c. Patient has had prior surgery for nasal polyps; **AND**
vi. Nucala is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).

B. Patient is Currently Receiving Nucala. Approve for 1 year if the patient meets the following criteria (i, ii, **and** iii):

i. Patient has already received at least 6 months of therapy with Nucala; **AND**
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Nucala should be considered under criterion 4A [Nasal Polyps, Initial Therapy]).

ii. Patient continues to receive therapy with an intranasal corticosteroid; **AND**
iii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Nucala therapy are reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell.

References:

1. Nucala® subcutaneous injection [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; July 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	December 2021