Nucala® is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype. NUCALA is also indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA). The drug is administered as a subcutaneous (SC) injection.

**Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Asthma</strong></td>
<td>− For patients ≥ 12 years of age, approve 100 mg administered subcutaneously once every 4 weeks; OR</td>
</tr>
<tr>
<td></td>
<td>− For pediatric patients (6 to 11 years of age), approve 40 mg administered subcutaneously once every 4 weeks.</td>
</tr>
<tr>
<td><strong>Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome]</strong></td>
<td>− Approve 300 mg administered subcutaneously once every 4 weeks.</td>
</tr>
<tr>
<td><strong>Hypereosinophilic Syndrome</strong></td>
<td>− Approve 300 mg administered subcutaneously once every 4 weeks.</td>
</tr>
</tbody>
</table>

**Length of Authorization**

- Initial approval:
  - Asthma and Eosinophilic Granulomatosis with Polyangiitis (EGPA)
    - Coverage will be provided for 6 months and may be renewed.
Hypereosinophilic Syndrome

- Coverage will be provided for 8 months and may be renewed.

Renewal:
- Coverage will be provided for 12 months.

Guideline

Asthma

a) Patient is ≥ 6 years of age; AND
b) Nucala is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; AND
c) Patient has a blood eosinophil level of ≥ 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 therapy include Nucala, Cinqair, and Fasenra.
d) Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
   a. An inhaled corticosteroid; AND
   b. At least one additional asthma controller/maintenance medication; AND
   Note: An exception to the requirement for a trial of one additional asthma controller/maintenance medication (criterion b) can be made if the patient has already received anti-interleukin-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an inhaled corticosteroid for at least 3 consecutive months. Examples of additional asthma controller/maintenance medications are inhaled long-acting beta2-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta2-agonist would fulfill the requirement for both criteria a and b.

- Patient’s asthma is uncontrolled or was uncontrolled prior to starting any anti-interleukin therapy as defined by ONE of the following:
  a. The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
  b. The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
  c. Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; OR
  d. Patient has an FEV₁/forced vital capacity (FVC) < 0.80; OR
  e. The patient’s asthma worsens upon tapering of oral corticosteroid therapy.
   Note: Examples of anti-interleukin therapies include Nucala, Cinqair, and Fasenra.

Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome].

- Patient is ≥ 18 years of age; AND;
- Nucala is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist; AND
- Patient has tried therapy with a corticosteroid (e.g., prednisone) for a minimum of 4 weeks; AND
- Patient has/had a blood eosinophil level of ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy.
   Note: Examples of anti-interleukin-5 therapies include Nucala, Cinqair, and Fasenra.

Hypereosinophilic Syndrome

- Patient is ≥ 12 years of age; AND
• Patient has had hypereosinophilic syndrome for ≥ 6 months; **AND**
• Patient has FIP1L1-PDGFRα-negative disease; **AND**
• According to the prescriber, the patient does NOT have an identifiable non-hematologic secondary cause of hypereosinophilic syndrome; **AND**

**Note:** Examples of secondary causes of hypereosinophilic syndrome include drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy.
• Prior to initiating therapy with any anti-interleukin-5 therapy, the patient has/had a blood eosinophil level of ≥ 1,000 cells per microliter; **AND**

**Note:** Examples of anti-interleukin-5 therapies include Nucala, Cinqua, and Fasenra.
• 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.
• Nucala is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist;

**Coverage for Nucala may be renewed when the following criteria are met:**

**Asthma**
• The patient has already received at least 6 months of therapy with Nucala; **AND**

**Note:** Patients who have received < 6 months of therapy or those who are restarting therapy with Nucala should be considered new to therapy – see above criteria.
• Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**

**Note:** Examples of an inhaled corticosteroid or an inhaled corticosteroid-containing combination inhaler include Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twister/HFA, Aerospan, Alvesco, Pulmicort Flexhaler, budesonide suspension for inhalation (Pulmicort Respules, generics), Qvar/Qvar RediHaler, Advair Diskus/HFA (generic Wixela Inhup; authorized generics), AirDuo RespiClick (authorized generics), Breo Ellipta, Dulera, and Symbicort.
• The patient has responded to Nucala 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 (ED)/urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

**Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome]**
• The patient has already received at least 6 months of therapy with Nucala; **AND**

**Note:** Patients who have received < 6 months of therapy or those who are restarting therapy with Nucala should be considered new to therapy – see above criteria.
• The patient has responded to Nucala 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.

**Hypereosinophilic Syndrome**
• The 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 new to therapy – see above criteria.
• The patient has responded to Nucala 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.

Limitations/Exclusions

- Atopic Dermatitis
- Chronic Obstructive Pulmonary Disease (COPD)
- Concurrent use of Nucala with another Anti-Interleukin (IL) Monoclonal Antibody
- Concurrent use of Nucala with Xolair® (omalizumab injection for subcutaneous use)
- Eosinophilic Esophagitis (EoE), Eosinophilic Gastroenteritis, or Eosinophilic Colitis
- Nasal polyps
- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2182</td>
<td>Injection, mepolizumab, 1 mg</td>
</tr>
</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>00173-0881-xx</td>
<td>Nucala single use vial; 100 mg powder for solution</td>
</tr>
<tr>
<td>00173-0892-xx</td>
<td>Nucala 100 mg/1 ml prefilled syringe for injection</td>
</tr>
</tbody>
</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.52</td>
<td>Severe persistent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J82</td>
<td>Pulmonary eosinophilia, not elsewhere classified</td>
</tr>
<tr>
<td>M30.1</td>
<td>Polyarteritis with lung involvement [Churg-Strauss]</td>
</tr>
</tbody>
</table>

Revision History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/2021</td>
<td>Criteria apply to Commercial, Medicare, and Medicaid members.</td>
</tr>
<tr>
<td>10/28/2020</td>
<td>Added “Hypereosinophilic Syndrome” to “FDA-Approved Indications”. Removed “Hypereosinophilic Syndrome” from “Conditions Not Recommended for Approval”.</td>
</tr>
</tbody>
</table>

References


6. FDA advisory committee meeting briefing document: Nucala (mepolizumab) for treatment of patients with severe asthma with eosinophilic inflammation. GlaxoSmithKline, LLC.; 2015 May


