Pharmacy Medical Necessity Guidelines: Nucala® (mepolizumab)

Effective: January 15, 2018

<table>
<thead>
<tr>
<th>Prior Authorization Required</th>
<th>√</th>
<th>Type of Review – Care Management</th>
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<td>Type of Review – Clinical Review</td>
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<tr>
<th>Pharmacy (RX) or Medical (MED) Benefit</th>
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<th>Department to Review</th>
<th>PRECERT/MM</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**Fax Numbers:**
- All plans except Tufts Health Public Plans: PRECERT: 617.972.9409
- Tufts Health Public Plans only: MM: 888.415.9055

**Note:** For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for:
- **Maintenance treatment of severe asthma**
  
  The add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Nucala (mepolizumab) is not indicated for the relief of acute bronchospasm or status asthmaticus.

- **Eosinophilic granulomatosis with polyangiitis**
  
  The treatment of adult patients with eosinophilic granulomatosis with polyangiitis.

**COVERAGE GUIDELINES**

The plan may authorize coverage of Nucala (mepolizumab) for Members when all of the following criteria are met:

**Maintenance treatment of severe asthma**

1. The Member has a documented diagnosis of severe eosinophilic asthma
   - **AND**

2. The Member has a pre-treatment serum eosinophil count of ≥150 cells/mcL at screening (within the past 6 weeks prior to initiation of the requested agent), OR ≥300 cells/mcL within 12 months prior to use, OR sputum eosinophilic count greater than 3%
   - **AND**

3. The prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist)
   - **AND**

4. The Member is 12 years of age or older
   - **AND**

5. The underlying conditions or triggers for asthma or pulmonary disease are being maximally managed
   - **AND**

6. Clinical documentation of poor asthma control or recurrent exacerbations requiring additional treatment is received
   - **a)** Additional medical treatment may include any of the following: treatment with oral corticosteroids, emergency department visits, hospitalizations, or frequent office visits
   - **b)** Poor asthma control may include but is not limited to clinical documentation of limitation in activities of daily living, nighttime awakening or dyspnea
   - **c)** Recurrent exacerbation is defined as 2 or more acute exacerbations in a 12 month period.

   - **AND**
7. One of the following:
   a) The Member’s symptoms are not well controlled or poorly controlled despite an adherent ≥ 3 month trial of high-dose inhaled corticosteroids (ICS) in combination with a long-acting inhaled beta-2 agonist (LABA), leukotriene modifier or theophylline or the Member is intolerant or has a contraindication to all of these medications OR
   b) The Member has experienced ≥ 2 exacerbations in the previous 12 months requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite an adherent ≥ 3 month trial of high-dose inhaled corticosteroids (ICS) in combination with a long-acting inhaled beta-2 agonist (LABA), leukotriene modifier or theophylline prior to the exacerbation or the Member is intolerant or has a contraindication to all of these medications.

   Note: An adherent trial is defined as a medication possession ratio (MPR) ≥ 70% based on the previous 120 days of prescription claims (records will be required for approval)

   Eosinophilic granulomatosis with polyangiitis
   1. The Member has a documented diagnosis of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following diagnostic criteria
      a) Asthma
      b) Eosinophilia (>10% eosinophils on the differential leukocyte count)
      c) Mononeuropathy or polyneuropathy
      d) Migratory or transient pulmonary infiltrates on chest x-rays
      e) Paranasal sinus abnormalities
      f) Biopsy containing a blood vessel with extravascular eosinophils
   AND
   2. The prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist) or rheumatologist
   AND
   3. The Member is 18 years of age or older
   AND
   4. The Member is stable on corticosteroids or the prescriber has indicated clinical inappropriateness of corticosteroid therapy
   AND
   5. Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy
   AND
   6. Documented trial and failure of, contraindication to, or clinical inappropriateness with treatment with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate
APPENDIX

1. NHBLI Estimated Comparative Daily Dosages for Inhaled Corticosteroids in Adults

<table>
<thead>
<tr>
<th>Drug</th>
<th>High Daily Dose (Adult ≥ 12 years old)</th>
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<tbody>
<tr>
<td>Beclomethasone HFA 40 or 80 mcg/puff</td>
<td>&gt;480 mcg</td>
</tr>
<tr>
<td>Budesonide DPI 90, 180 or 200 mcg/inhalation</td>
<td>&gt;1,200 mcg</td>
</tr>
<tr>
<td>Budesonide Inhaled Inhalation suspension for nebulization</td>
<td>NA</td>
</tr>
<tr>
<td>Ciclesonide HFA 80 or 160 mcg</td>
<td>&gt;640 mcg</td>
</tr>
<tr>
<td>Flunisolide HFA 80 mcg/puff</td>
<td>&gt;640 mcg</td>
</tr>
<tr>
<td>Fluticasone HFA/MDI: 44, 110, 220 mcg/puff</td>
<td>&gt;440 mcg</td>
</tr>
<tr>
<td>Fluticasone DPI: 50, 100, 250 mcg/inhalation</td>
<td>&gt;500 mcg</td>
</tr>
<tr>
<td>Mometasone DPI 200 mcg/inhalation</td>
<td>&gt;400 mcg</td>
</tr>
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DPI: dry powder inhaler, HFA: hydrofluoroalkane, MDI: metered-dose inhaler, NA: not available (either not approved, no data available, or safety and efficacy not established at this age group)

LIMITATIONS

1. The member will not receive the requested agent in combination with another interleukin 5 (IL-5) inhibitor indicated for asthma.

2. Other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out.

3. For maintenance treatment of severe asthma:
   a) Initial authorization of Nucala (mepolizumab) may be provided for six months.
   b) Reauthorization of Nucala (mepolizumab) may be provided for 12 months for Members 12 years of age and older, who are not receiving the requested agent in combination with another interleukin 5 inhibitor indicated for asthma, with documentation of the diagnosis of severe eosinophilic asthma with medical chart documentation that the Member has experienced a sustained clinical response to Nucala (mepolizumab) by one or more of the following:
      i. Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pretreatment)
      ii. Reduction in the dose of inhaled corticosteroids required to control the patient’s asthma
      iii. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits),
      iv. Reduction in the use of oral corticosteroids to treat/prevent exacerbations, or
      v. Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath, or nocturnal awakenings.
   c) Annual reauthorization requires medical chart documentation that the patient has been seen within the previous 14 months and there is continued documented benefit from using Nucala (mepolizumab).

4. For eosinophilic granulomatosis with polyangiitis, authorizations may be provided for 12 months. Reauthorization requires documentation of sustained severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid or immunotherapy therapy.

CODES

The following HCPCS/CPT code(s) are:

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


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


14. Talmadge EK. Clinical features and diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).

15. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).

APPROVAL HISTORY

May 10, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- January 1, 2017: Administrative update: added new J code (J2182) to Medical Necessity Guideline and removed expired C code (C9473).
- May 9, 2017: No changes
- January 9, 2018: Added coverage criteria for the new indication of eosinophilic granulomatosis with polyangiitis.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s
benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.