I. Policy:
Nucala vial (mepolizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Nucala vial (mepolizumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Revised – the date the policy was implemented.
4. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Nucala (mepolizumab) is an interleukin-5 antagonist (immunoglobulin G1 [IgG1] kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and an important component of the pathogenesis of asthma). Mepolizumab, by inhibiting interleukin-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Nucala vial (mepolizumab) will be considered medically necessary when all of the following criteria are met:

**Severe Eosinophilic Asthma**
- Documentation of patient age ≥ 6 years AND
- Medical record documentation of a diagnosis of severe eosinophilic asthma AND that Nucala is being used as add-on maintenance treatment AND
- Prescription written by an allergist or pulmonologist AND
- Medical record documentation of a blood eosinophil count of either > 300 cells/mcL during the 12-month period before screening and/or > 150 cells/mcL within 3 months of the start of therapy AND
- Medical record documentation of:
  - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3 month trial of: high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist OR
  - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist AND
- Insured individual must be adherent with current therapeutic regimen and must demonstrate appropriate inhaler technique AND
- Known environmental triggers within the member’s control have been eliminated AND
- Medical record documentation that Nucala is not being used in combination with Fasenra (benralizumab), Cinqair (reslizumab), or Xolair (omalizumab).

*Measures of disease severity

<table>
<thead>
<tr>
<th>Measure</th>
<th>Not Well Controlled</th>
<th>Very Poorly Controlled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptoms</td>
<td>&gt; 2 days per week</td>
<td>Throughout the day</td>
</tr>
<tr>
<td>Nighttime awakenings</td>
<td>1-3x/week</td>
<td>≥ 4x/week</td>
</tr>
<tr>
<td>Interference with normal activity</td>
<td>Some limitation</td>
<td>Extremely limited</td>
</tr>
<tr>
<td>SABA use for symptom control (not to prevent exercise-induced bronchospasm)</td>
<td>&gt; 2 days/week</td>
<td>Several times per day</td>
</tr>
<tr>
<td>FEV1 (% predicted) or peak flow (% personal best)</td>
<td>60-80%</td>
<td>&lt; 60%</td>
</tr>
<tr>
<td>Asthma Control Test (ACT) Score</td>
<td>16-19</td>
<td>&lt; 15</td>
</tr>
</tbody>
</table>

**Eosinophilic Granulomatosis (EGPA)**
- Prescription written by an allergist/immunologist, pulmonologist, and/or rheumatologist AND
- Medical record documentation that patient is ≥18 years of age AND
- Medical record documentation of eosinophilic granulomatosis (EGPA) confirmed by biopsy evidence of vasculitis AND at least four (4) of the following criteria:
  - Asthma (a history of wheezing or the finding of diffuse high-pitched wheezes on expiration)
  - Eosinophilia (blood eosinophil level of ≥10% or ≥1500 cells/microL on differential white blood cell count)
  - Mononeuropathy (including multiplex) or polyneuropathy
  - Migratory or transient pulmonary opacities detected radiographically
  - Paranasal sinus abnormality
  - Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas

AND
- Medical record documentation of a therapeutic failure on, contraindication to, or intolerance to systemic glucocorticoid therapy AND at least one immunosuppressant therapy (cyclophosphamide, azathioprine, methotrexate)

**Quantity Limit:** 1 vial (100mg) per 28 days (for eosinophilic asthma), 3 vials (300mg) per 28 days (for EGPA)
**AUTHORIZATION DURATION:** Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

**LIMITATIONS:**
- Nucala is not indicated for the relief of acute bronchospasm or status asthmaticus.

**LINE OF BUSINESS:**
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 3/15/2016

**Revised:** 5/15/18 (EGPA added), 11/19/19 (age for asthma, vials)

**Reviewed:** 2/28/17, 1/24/18, 4/22/19