I. Medication Description

Mepolizumab is an interleukin-5 antagonist (IgG1 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Mepolizumab binds to IL-5 with a dissociation constant of 100 pM, inhibiting the bioactivity of IL-5 by blocking its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface. Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, cytokines) are involved in inflammation. Mepolizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of mepolizumab action in asthma has not been definitively established.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided for the following conditions when the listed criteria are met:

- Severe uncontrolled asthma with an eosinophilic phenotype:
  - Member is at least 12 years of age AND
  - Medication is prescribed by an allergist/immunologist, or pulmonologist AND
  - Member has a history of two or more exacerbations resulting in either emergency department visits or need for pulse oral or IV corticosteroids in the past 12 months AND
  - These exacerbations occurred despite regular use of high-dose inhaled corticosteroids plus an additional controller(s) AND
  - Member has eosinophilic asthma, indicated by at least one of the following:
    - Blood eosinophils of greater than or equal to 150 cells/μL within 6 weeks of Nucala initiation OR
    - Blood eosinophils of greater than or equal to 300 cells/μL within 12 months of Nucala initiation AND
  - Coverage of Nucala is not available in combination with Xolair.

- Eosinophilic granulomatosis with polyangiitis (EGPA):
  - Member is at least 18 years of age AND
  - Member has a documented relapsing or refractory disease AND
o Member has tried and failed a corticosteroid treatment (unless contraindicated) or Nucala is used in addition to corticosteroids AND
o Member has a history or the presence of an eosinophil count of more than 1000/μL or a blood eosinophil level of greater than 10%.

IV. **Quantity Limitations**

Coverage is available as follows:
- For the treatment of severe asthma: 100mg every 4 weeks
- For the treatment of EGPA: 300mg every 4 weeks

V. **Coverage Duration**

Coverage can be provided for 12 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

- Available as 100mg single-dose vial of lyophilized powder for reconstitution
- J2182 - 1 billable unit is 1 mg
- Pertinent diagnosis
  - eosinophilic asthma: J82
  - polyarteritis with lung involvement [EGPA/Churg-Strauss]: M30.1

VIII. **Summary of Policy Changes**

- 3/15/16: new policy
- 1/1/17: no policy changes
- 1/1/18: billing code updated
- 5/1/18: added new indication for the treatment of EGPA; updated quantity limitation and billing/coding information

IX. **References**


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.