I. Medication Description

Nucala (mepolizumab) is an interleukin-5 antagonist indicated for add-on maintenance treatment of severe asthma with an eosinophilic phenotype and for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA), which is also known as Churg-Strauss syndrome.

Inflammation is a major component in the pathogenesis of asthma and eosinophilic granulomatosis with polyangiitis (EGPA), and many cell types and mediators are involved in inflammation. Mepolizumab is a fully humanized monoclonal antibody (IgG1 kappa) that targets human interleukin (IL)-5. IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Mepolizumab selectively binds to IL-5, blocking it from binding to the alpha chain of the IL-5 receptor complex located on the eosinophil cell surface. This, in turn, inhibits IL-5 signaling and reduces the production and survival of eosinophils.

II. Position Statement

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

When administered by a healthcare professional, Nucala is considered a medical benefit. In all other situations, Nucala is considered a pharmacy benefit.

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 6 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**
iv. Quantity Limitations

Coverage is available as follows:
- For the treatment of severe asthma: one 100mg dosage form (vial/autoinjector/syringe) 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 (medical benefit only)
  - 100mg/mL single-dose prefilled autoinjector (medical and pharmacy benefit)
  - 100mg/mL single-dose prefilled syringe (medical and pharmacy benefit)
- 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
• 1/15/19: no policy changes
• 6/28/19: added autoinjector and prefilled syringe formulations; updated policy to add coverage under pharmacy benefit; updated billing/coding information
• 11/15/19: no policy changes
• 1/30/20: updated age for the treatment of asthma; clarified quantity limitations

IX. References


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual

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.