Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	May 8, 2018

NUCALA® (mepolizumab)

LENGTH OF AUTHORIZATION: Initial: SIX MONTHS Continuation: ONE YEAR

CLINICAL NOTES: Nucala® (mepolizumab) is a human monoclonal antibody indicated for add-on maintenance in the treatment of severe eosinophilic asthma in individuals 12 years of age and older, and for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA, formerly known as Churg-Strauss syndrome) in adults. It is administered by a healthcare provider.

REVIEW CRITERIA:

INITIAL REVIEW:

Specific Review Criteria Maintenance Treatment of Severe Asthma

- Patient is 12 years of age or older.
- Prescribed or in consultation with an allergist, pulmonologist, or immunologist.
- Verified diagnosis of severe persistent asthma; must be an eosinophilic phenotype.
- Must have a blood eosinophil count of ≥ 150 cells/mcL within the past six weeks while on oral corticosteroid or ≥ 300 cells/mcL within the past year (submit documentation).
- Must have adherence to optimized medication therapy regimen, yet uncontrolled:
  - Hospitalization for asthma within the past year; OR
  - Two occurrences in the past year requiring systemic corticosteroids (oral or parenteral) to control exacerbations of asthma; OR
  - Daily use of corticosteroids with inability to taper off the medication.
- Trial of high dose inhaled corticosteroids and one of the following:
  - Inhaled long acting beta 2-agonist
  - theophylline
  - leukotriene receptor antagonist

Specific Review Eosinophilic Granulomatosis with Polyangiitis

- Patient is 18 years of age or older.
- Verified diagnosis of eosinophilic granulomatosis with polyangiitis.
- Prescribed or in consultation with an allergist, pulmonologist, or immunologist.
- Must have an adequate trial of a minimum of three months of the following, with an inadequate response or significant side effects/toxicity to therapy:
  - Corticosteroids; AND
  - An immunosuppressant such as azathioprine or methotrexate.

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CONTINUATION OF THERAPY:

Severe Asthma

- Patient has met initial review requirements.
- Improvement of asthma while on current regimen including Nucala® through:
  - A reduction in the frequency or severity of symptoms or exacerbations; OR
  - A reduction in the daily maintenance oral corticosteroid dose; OR
  - A reduction in the number of rescued medications; OR
  - A reduction in the number of hospitalizations or emergency room visits.

Eosinophilic Granulomatosis with Polyangiitis

- Patient has met initial review requirements.
- Patient has seen a response to therapy by the following:
  - Reduction in frequency of relapses; OR
  - No active vasculitis; OR
  - A reduction in the dose of daily oral corticosteroids.

DOSING:

Severe Asthma:

The recommended dosage of Nucala® is 100mg administered subcutaneously once every 4 weeks into the upper arm, abdomen or thigh. It is administered by a healthcare provider.

Eosinophilic Granulomatosis with Polyangiitis:

The recommended dosage of Nucala® is 300 mg administered subcutaneously once every 4 weeks as 3 separate 100-mg injections into the upper arm, thigh, or abdomen. It is administered by a healthcare provider.