STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

Nucala® (mepolizumab)
Effective 10/01/2019

Prior Authorization Request Form

NUCALA is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Prior authorization requests for Nucala may be approved if the following criteria are met:

TREATMENT OF EOSINOPHILIC ASTHMA:

1. Must be prescribed by or in consultation with an allergist, immunologist or pulmonologist; **AND**

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient must have documented adherence to a therapeutic regimen consisting of a LABA + high dose ICS therapy in the last 90 days; **AND**

4. Documentation must be supplied indicating **one** of the following:
    a. A positive sputum test for eosinophilic phenotype asthma with sputum eosinophil level ≥ 3% **OR**
    b. Asthma with eosinophilic phenotype with blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months
    c. **OR** claims data that reflect a continual reliance on oral corticosteroid therapy in the last 90 days.

Initial approval of Nucala for asthma will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response and compliance on inhaled therapy.

TREATMENT OF EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA):

1. Patient must have a documented diagnosis of EPGA (also known as Churg-Strauss Syndrome) with the patient meeting at least 4 of the following diagnostic criteria:
    a. Asthma
    b. Eosinophilia of > 10% in peripheral blood
    c. Paranasal sinusitis
    d. Pulmonary infiltrates, sometimes transient

e. Histologic evidence of vasculitis with extravascular eosinophils
f. Multiple mononeuropathy or polyneuropathy

AND

2. The patient must be within the age range as recommended by the FDA label and indication; **AND**

3. Patient has failed to achieve remission of symptoms following at least a 90-day course of systemic glucocorticoid therapy equivalent to (or greater than) 7.5 mg/day of oral prednisone PLUS immunosuppressive therapy such as, but not restricted to, cyclophosphamide, methotrexate or azathioprine (unless contraindicated) *

   * If the provider feels that immunosuppressive therapy is contraindicated, they must document the reason for this.

Initial approval of Nucala for EGPA will be for 90 days. Additional therapy shall be approvable with documentation of satisfactory patient response.

References

1.) Nucala Package Insert (06/2019)
2.) LexiComp monograph review (09/06/2019)
3.) UpToDate review: Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss) – Last updated 11/29/2018
4.) UpToDate literature review on the treatment of severe asthma in adolescents and adults (11/07/2018)
5.) American College of Rheumatology – Arthritis and Rheumatism, Vol. 33, No. 8 (August 1990) The American College of Rheumatology 1990 Criteria for the Classification of Churg-Strauss Syndrome (Allergic Granulomatosis and Angiitis)