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

Office of Pharmacy Services
Prior Authorization Criteria
Nucala® (mepolizumab)
Effective 1/01/2022

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).
- Treatment of adult and pediatric patients ≥12 years of age with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable nonhematologic secondary cause.
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with an inadequate response to nasal corticosteroids.

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 150 cells/mcL within the past 6 weeks or blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; **OR**
    c. 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.

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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.

TREATMENT OF HYPEREOSINOPHILIC ASTHMA:

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

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

3. The patient must have a blood eosinophil count of ≥ 1,000 cells per mcl; **AND**

4. The patient has had at least 2 HES flares within the past 12 months; **AND**

5. The patient is on a stable dose of background HES therapy (chronic or episodic corticosteroids, immunosuppressive, or cytotoxic therapy) for at least 4 weeks prior to treatment initiation.

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

Updated: DUR meeting 11/17/2021 for effective date 1/1/2022 PS
DUR Board Approval: 09/25/2019

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TREATMENT OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**

2. The patient must have a diagnosis of chronic rhinosinusitis with nasal polyps which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**

3. The patient must be within the approved age range according to the FDA label and indication; **AND**

4. Nucala is only approvable as add-on therapy for CRSwNP.

Initial approval of Nucala for CRSwNP will be for 90 days. Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Nucala was supplementing).

References:

1.) Nucala Package Insert 06/2019, 11/2021
2.) LexiComp monograph review 09/06/2019, 11/2021
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)

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