



MONTANA HEALTHCARE PROGRAMS

January 16, 2019

Physician Administered Drug Prior Authorization Criteria for Nucala®

Version 1 published 01-16-19

Version 2 published 11-22-2017

Nucala® (mepolizumab) is an interleukin-5 antagonist monoclonal antibody

Indications: Nucala® is used for:

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

Length of Authorization-1 year

Criteria for Approval:

For Eosinophilic Asthma:

- Must be prescribed by an appropriate specialist or have an annual consult on file. (allergist, pulmonologist or immunologist).
- Member is 12 years of age or older
- Member must have severe uncontrolled asthma with an eosinophilic phenotype (confirmed)
- Member must be appropriately using ICS and LABA inhalers

For EGPA:

- Must be prescribed by an appropriate specialist or have an annual consult on file. (rheumatologist, pulmonologist or immunologist).
- Member is 18 years of age or older
- Must have diagnosis of EPGA. Include supporting documentation and biopsy confirmation with PA request.
- Must have had diagnosis of EPGA for 6 months with a history of relapsing or refractory disease.
- Member is experiencing exacerbations while on a stable dose of oral corticosteroid or during steroid taper.
- Immunosuppressive therapy has been ineffective, contraindicated, or not tolerated. Include supporting documentation.

Limitations:

Eosinophilic Asthma: max of 100mg SQ every 4 weeks. **EGPA:** max of 300mg SQ every 4 weeks.

Renewal Criteria:

- Member must have been adherent to treatment regimen during the previous year (including ICS and LABA for asthma).
- Member has had a positive response to therapy as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations, or medication dose reduction.

References:

1. Nucala® [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; 12/2017, Accessed December 26, 2018.
2. King, T. (11/29/18) Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). In H. Hollingsworth (Ed.), *UpToDate*. Retrieved December 26, 2018, from https://www.uptodate.com/contents/treatment-and-prognosis-of-eosinophilic-granulomatosis-with-polyangiitis-churg-strauss?search=egpa&source=search_result&selectedTitle=2~131&usage_type=default&display_rank=2