Mepolizumab (Nucala®)
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

Policy

Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for:

- The add-on maintenance treatment of patients with severe asthma, aged 12 years and older, with an eosinophilic phenotype
- Eosinophilic granulomatosis with polyangiitis in adults.
- Approval for Nucala will be granted when **ALL** criteria and conditions have been met and documentation has been submitted.

Nucala is **NOT** indicated for the relief of acute bronchospasm or status asthmaticus.

Approval Criteria

Severe Asthma:

1. Member has documented diagnosis of severe asthma with an eosinophilic phenotype
2. Member is not an active smoker
3. Member has a pre-treatment serum eosinophil count of ≥150 cells/mcL (within the past 6 weeks prior to initiation of Nucala) OR historical level of ≥300 cells/mcL in the last 12 months if it is documented that the member is currently on oral steroids.
4. Member must be maintained on and adherent to (taking at least 80% of daily doses) of controller medications (***high dose*** inhaled steroids listed in **Appendix A**, in combination with a long-acting inhaled beta-2 agonist and a leukotriene modifier) for at least 4 months† **OR**
5. Member is intolerant or has a contraindication to all controller medications.
6. Despite adherence to controller medications, member has experienced at least 2 of the following in the past 12 months:
   - Two or more exacerbations requiring oral steroid therapy for at least four days
   - Two or more exacerbations requiring hospitalization or emergency Department visit
   - Airflow limitation (FEV1 less than 60% predicted)
   - Daily symptoms such as cough, wheezing, chest tightness or difficulty breathing
7. Prescriber is an allergist, immunologist or pulmonologist
8. Prescriber must confirm that Nucala will be administered only in a healthcare setting

Eosinophilic granulomatosis with polyangiitis

1. Member has a documented diagnosis of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following diagnostic criteria:
   a) Asthma
   b) Eosinophilia (>10% eosinophils on the differential leukocyte count)
   c) Mononeuropathy or polyneuropathy
   d) Migratory or transient pulmonary infiltrates on chest x-rays
   e) Paranasal sinus abnormalities
   f) Biopsy containing a blood vessel with extravascular eosinophils

2. Prescriber is an allergist, immunologist, pulmonologist or rheumatologist
3. Member is 18 years of age or older
4. Member is stable on corticosteroids or the prescriber has submitted clinical rationale why corticosteroid therapy is not appropriate
5. Documentation of severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy
6. Member has experienced an inadequate response or has contraindication to treatment with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate OR prescriber has submitted clinical information why these medications are not appropriate.
7. Prescriber must confirm that Nucala will be administered only in a healthcare setting

APPENDIX A: Comparative Daily Dosages for Inhaled Corticosteroids in Adults

Medication	Adult Daily High Doses
Beclomethasone MDI	>480 mcg
Budesonide DPI	>1,080 mcg
Ciclesonide MDI	>640 mcg
Flunisolide MDI	>640 mcg
Fluticasone MDI	>440 mcg
Fluticasone DPI	>500 mcg
Mometasone DPI	>440 mcg

†Adherence is defined as prescription fills of at least 70% during the previous 120 days

Initial approvals for both indications will be granted for 4 months: If a member does not respond within 4 doses of initiating treatment, it is unlikely that further administration of mepolizumab will be beneficial.

Reauthorization criteria:

Severe Asthma

Continued treatment with Nucala may be approved for 12 months when clinical documentation is submitted showing member has been seen and evaluated within the past 12 months and the member has continued to experience a positive clinical response as evidenced by at least two of the following:

- Increase in percent predicted (FEV1) from baseline (pretreatment)
- Reduction in the dose of inhaled corticosteroids required to control the member's asthma
- Reduction in asthma exacerbations (e.g., decreased frequency of emergency department/urgent care visits),
- Reduction in the use of oral corticosteroids to treat/prevent exacerbations
- Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath, or nighttime awakenings.

Eosinophilic granulomatosis with polyangiitis:

Continued treatment with Nucala may be approved for 12 months when clinical documentation is submitted showing member has had improvement in condition or member continues to have sustained severe disease (e.g. vasculitis with cerebral, cardiac, renal or gastrointestinal involvement) or condition flares upon tapering of steroid or immunosuppressant therapy**.**

Cautions

1. **Opportunistic Infections:** Herpes zoster infections have occurred in patients receiving mepolizumab. Consider varicella vaccination if medically appropriate prior to starting therapy.
2. **Parasitic (Helminth) Infection:** Treat patients with pre-existing helminth infections before therapy with mepolizumab. If patients become infected while receiving treatment with mepolizumab and do not respond to anti-helminth treatment, discontinue mepolizumab until parasitic infection resolves.

References

1. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017
2. National Heart, Lung, and Blood Institute (NHLBI/NIH). Guidelines for the Diagnosis and Management of Asthma (EPR-3). URL: nhlbi.nih.gov/health-pro/guidelines/current/asthmaguidelines. Available from internet. Accessed 2016 April 2018
3. Wechsler ME, Akuthota P, Jayne D, et al; EGPA Mepolizumab Study Team. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. *N Engl J Med*. 2017;376(20):1921-1932.[PubMed 28514601]
4. Ortega HG, Mark SD, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Eng J Med.. 2014; 371: 1198-1207
5. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (ChurgStrauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).