Mepolizumab (Nucala®)
Effective January 1, 2020

Plan	☐ MassHealth ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

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 and Eosinophilic granulomatosis with polyangiitis in adults.

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

Coverage Guidelines

Severe Asthma

1. Authorization may be granted for members who are currently receiving treatment with Nucala excluding when the product is obtained as samples or via manufacturer's patient assistance program
   OR
2. Authorization may be granted for members with severe asthma who meet all the following criteria and documentation has been provided:
   a. The member has documented diagnosis of severe asthma with an eosinophilic phenotype
   b. The member is ≥ 12 years of age
   c. The member is not an active smoker
   d. The member has a pre-treatment serum eosinophil count of ≥150 cells/µL (prior to initiation of Nucala) OR historical level of ≥300 cells/ µL in the last 12 months if it is documented that the member is currently on oral steroids.
   e. The member is symptomatic despite receiving one of the following:
      - combination inhaler containing an inhaled corticosteroid and a long-acting β-agonist

- combination of an inhaled corticosteroid and a long-acting β-agonist inhaler as separate inhalers
- chronic oral corticosteroids

Eosinophilic granulomatosis with polyangiitis

1. Authorizations may be granted for members who meet all the following criteria and documentation has been provided:
    a. The member is ≥ 18 years of age;
    b. The member has a diagnosis of Eosinophilic granulomatosis with polyangitis
    c. The member has had an inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to one systemic glucocorticoid
    d. The member has had an inadequate response (defined as ≥ 30 days of therapy), adverse reaction, or contraindication to azathioprine or methotrexate
    e. The prescriber is a specialist (i.e., allergist, immunologist, pulmonologist, rheumatologist)
        - dose is appropriate (300 mg subcutaneously every four weeks).

Continuation of Therapy

Severe Asthma

Reauthorization may be approved 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

Reauthorization may be approved 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.

Limitations

1. Initial approvals will be granted for 4 months
    a. If a member does not respond within 4 doses of initiating treatment, it is unlikely that further administration of mepolizumab will be beneficial.
2. Reauthorizations will be granted for 12 months
3. The following quantity limits apply

Nucala auto-injector 100mg/ml	3 per 28 days
Nucala prefilled syringe 100mg/ml	3 per 28 days

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; September 2019
2. Smetzer J, Cohen M, Shastay A, Jenkins R, Litman, RS, eds. Check for proper Nucala dose preparation. *ISMP Medication Safety Alert! Acute Care Edition*. 2018;23(18):1-2
3. National Heart, Lung, and Blood Institute (NHLBI/NIH). Guidelines for the Diagnosis and Management of Asthma (EPR-3). URL: nhlbi.nih.gov/health-ro/guidelines/current/asthma guidelines. Available from internet. Accessed 2016 April 2018
4. Gunsoy NB, Cockle SM, Yancey SW, et al. Evaluation of Potential Continuation Rules for Mepolizumab Treatment of Severe Eosinophilic Asthma. J Allergy Clin Immunol Pract 2018; 6:874
5. 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]
6. Ortega HG, Mark SD, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Eng J Med. 2014; 371: 1198-1207
7. Talmadge EK. Treatment and prognosis of eosinophilic granulomatosis with polyangiitis (ChurgStrauss). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 26, 2017).

Review History

09/24/18 – Updated
11/20/19 – Updated to require only failure of separate ICS inhaler w/ LABA or combination product and removed requirement of DX based on diagnostic criteria

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