Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Nucala (mepolizumab)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2016***

Last P & T Committee Approval Date: *March 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Nucala (mepolizumab).

Nucala (mepolizumab) is indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype and treatment of adults with eosinophilic granulomatosis with polyangiitis.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Nucala (mepolizumab), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

1. *Severe asthma*

- Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Must be 12 years or older
- Must have a diagnosis of severe persistent asthma. Chart documentation must be provided.
- Dose should not exceed 100mg every 4 weeks
- Must have an eosinophilic phenotype
    - Must have a blood eosinophil count of > 150 cells/mcL within the past month while on oral corticosteroid or ≥ 300 cells/mcL within the past year. Test date must be provided.
- Must have asthma symptoms that have not been adequately controlled despite adherence to an optimized medication therapy regimen, defined by one of the following:
    - Hospitalization for asthma in the past year
    - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on 2 occurrences in the past year
    - On daily corticosteroid with inability to taper off
- Must have tried other add-on maintenance treatment with a high dose inhaled corticosteroid and two of the following:
    - Inhaled long-acting beta agonist
    - Inhaled long-acting muscarinic antagonist
    - Leukotriene receptor antagonist
    - Theophylline

2. *Eosinophilic granulomatosis with polyangiitis*

- Must be prescribed by or in consultation with an allergist, immunologist, pulmonologist, rheumatologist, or hematologist
- Must be 18 years or older
- Must have a diagnosis of eosinophilic granulomatosis with polyangiitis. Chart documentation must be provided.

- Must have an adequate trial of at least 3 months of the following with an inadequate response or significant side effects/toxicity or have a contraindication to therapy
    - Corticosteroids
    - An immunosuppressant such as azathioprine or methotrexate

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber of the following:

- The member's condition has improved based upon the prescriber's assessment while on therapy.
- For asthma request: Reduction in exacerbations, hospitalizations, emergency department visits, or requirement for oral corticosteroid therapy.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 1 year
Quantity Level Limit	
Nucala	3 vials per 28 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Nucala [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
2. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Engl J Med. 2014;371:1198-1207.
3. Eosinophilic Granulomatosis with Polyangiitis. American Partnership for Eosinophilic Disorders. http://apfed.org/about-ead/eosinophilic-granulomatosis-with-polyangiitis/
4. Eosinophilic Granulomatosis with Polyangiitis. National Institutes of Health. Genetic and Rate Diseases Information Center. https://rarediseases.info.nih.gov/diseases/6111/eosinophilic-granulomatosis-with-polyangiitis
5. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017;376:1921-1932.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/16, 02/17, 02/18*
New Indication	*03/18*