RX.PA.051.CCH NUCALA® (MEPOLIZUMAB)

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

Nucala® (mepolizumab) is indicated for the following:

- Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP)
- Treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA)
- The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause

DEFINITIONS

Severe Asthma – As defined by the European Respiratory Society (ERS)/American Thoracic Society (ATS), severe asthma is "asthma that requires treatment with high dose inhaled corticosteroids […] plus a second controller (and/or systemic corticosteroids) to prevent it from becoming 'uncontrolled' or which remains 'uncontrolled' despite this therapy".

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 Medical Policy Committee.

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

PROCEDURE

Initial Authorization Criteria:

Must meet all the criteria listed under the respective diagnosis:

1. **Severe Asthma**
   - Must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
   - Must be 6 years or older
   - Must have chart documentation supporting a diagnosis of severe persistent asthma

- 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)
        - Exceptions can be made for members on multiple oral steroids contributing to a reduced eosinophil count if chart documentation demonstrates symptoms are not controlled at baseline or while on a single oral steroid
- 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 a high dose inhaled corticosteroid (*see table 1 below*) in combination with **ONE** of the following:
    - Inhaled long-acting beta agonist
    - Inhaled long-acting muscarinic antagonist
    - Leukotriene receptor antagonist
    - Theophylline

Table 1: High daily metered doses of inhaled corticosteroids – adapted from GINA 2022 guidelines.

Inhaled corticosteroid (ICS)	Total Daily ICS High dose (mcg) Ages 6 to 11 years	Total Daily ICS High dose (mcg) Ages ≥12 years
Beclometasone diproprionate (pMDI, standard particle, HFA)	>400	>1000
Beclometasone diproprionate (DPI or pMDI, extrafine particle, HFA)	>200	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	>400	>800
Budesonide (nebules)	>1000	N/A
Ciclesonide (pMDI, extrafine particle, HFA)	>160	>320
Fluticasone furoate (DPI)	N/A	200
Fluticasone propionate (DPI, or pMDI, standard particle, HFA)	>200	>500
Mometasone furoate (pMDI, standard particle, HFA)	200	>400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

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)
- Dose should not exceed 300mg every 4 weeks
- 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 these therapies:
    - Corticosteroids
    - An immunosuppressant such as azathioprine or methotrexate

3. Hypereosinophilic syndrome (HES)

- Must be prescribed by or in consultation with an appropriate specialist such as allergist, immunologist, hematologist, or another specialist with experience in the treatment of HES
- Must be 12 years or older
- Must have a diagnosis of HES for six months or longer without another identifiable non-blood related cause of the disease such as drug hypersensitivity, parasitic helminth infection, HIV infection, and non-hematologic malignancy (chart documentation must be provided)
- Dose should not exceed 300mg every 4 weeks
- Blood eosinophil count must be 1,000 cells/mcL or higher
- Must have an adequate trial of the following with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies:
    - Corticosteroids (such as prednisone)
    - Hydroxyurea

4. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Must be 18 years or older
- Must be prescribed by an allergist, immunologist, or otolaryngologist (ENT)
- Dose should not exceed 100mg every 4 weeks
- Must have documentation of an adequate trial of TWO nasal corticosteroids with inadequate response or significant side effects/toxicity or have a contraindication tothese therapies
- Must be used as add-on maintenance treatment to current intranasal steroid therapy

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
- **Severe asthma only:** 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 1 year
Reauthorization	Same as initial
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, ifrequired for the plan and level of request.

HCPCS Codes:

HPCPS Code	Brand	Description
J2182	Nucala	INJECTION, MEPOLIZUMAB, 1 MG

REFERENCES

1. Nucala [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; October 2020.
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.
6. 2022 GINA Report, Global Strategy for Asthma Management and Prevention. Available from: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf
7. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Initial review	03/22
Updated initial authorization duration to 1 year; changed severe asthma prerequisite number to one required	04/23

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.

Disclaimer

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