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:

- **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, with the member meeting ONE of the following:

- Baseline blood eosinophil count of ≥150 cells/mL
- Member is dependent on systemic corticosteroids

- Dose should not exceed 100mg every 4 weeks
- Must have asthma symptoms that have not been adequately controlled on an optimized medication regimen, defined by **ONE** of thefollowing:
  - Hospitalization or emergency visit for asthma in the past year
  - Requirement for systemic (oral, parenteral) corticosteroids to control exacerbations of asthma on TWO 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 for ICS dosing guide*) in combination with **ONE** of the following:
  - Inhaled long-acting beta agonist
  - Inhaled long-acting muscarinic antagonist
  - Leukotriene receptor antagonist
  - Theophylline
- Must have documentation or attestation from the provider of the following:
  - Will not be used with another biologic or targeted synthetic drug for asthma, such as Xolair (omalizumab) or Cinqair (reslizumab)
  - The member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication

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

- **Eosinophilic Granulomatosis with Polyangiitis (EGPA)**
  - 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, with

chart note documentation showing the member has at least TWO of the following disease characteristics of EGPA:

- Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic
- infiltration, or eosinophil-rich granulomatous inflammation
- Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
- Pulmonary infiltrates, non-fixed
- Sino-nasal abnormality
- Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
- Glomerulonephritis (hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage (by bronchoalveolar lavage)
- Palpable purpura
- Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)

- Must have a current or historical eosinophil count of >1000 cells/mL **OR** a blood eosinophil level of >10%
- Dose should not exceed 300mg every 4 weeks
- Must be currently taking oral corticosteroids, unless contraindicated or not tolerated
- Must have had at least one relapse (i.e., requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication or has a refractory disease

- **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
  - Dose should not exceed 300mg every 4 weeks
  - Must have a historical or current blood eosinophil count of ≥ 1,000 cells/mcL
  - Must have had an adequate trial of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy)
  - Must have documentation or attestation from the provider of the following:
    - Member does not have either of the following:

        - HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy)
        - FIP1L1-PDGFRA kinase-positive HES
    - Member will not use the requested medication as monotherapy

- **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**
  - Must be 18 years or older
  - Must be prescribed by an allergist, immunologist, or otolaryngologist (ENT)
  - Must have a diagnosis of bilateral nasal polyps with documentation of at least ONE of the following:
    - Bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
    - Meltzer Clinical Score of 2 or higher in both nostrils
    - Total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
  - Must have documentation showing symptoms of nasal blockage, congestion, or obstruction plus ONE additional symptom below:
    - Rhinorrhea (anterior/posterior)
    - Reduction or loss of smell
    - Facial pain or pressure
  - Dose should not exceed 100mg every 4 weeks
  - Must have documentation of an adequate trial of nasal corticosteroids for at least TWO months with an inadequate response or significant side effects/toxicity or have a contraindication to these therapies
  - Must have documentation of ONE of the following:
    - Prior sino-nasal surgery
    - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
  - Must have documentation or attestation from the provider of the following:
    - That the requested medication will not be used with another biologic or targeted synthetic drug for CRSwNP, such as Xolair (omalizumab)
    - That the member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated

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 when the following criteria are met per diagnosis and :

- **Severe asthma**
  - Must have chart note documentation showing the member's asthma control has improved, as evidenced by either:
    - Reduction in the frequency and/or severity of symptoms and

exacerbations
- Reduction in the daily maintenance oral corticosteroid dose

- Must have documentation or attestation from the provider of the following:
  - That the member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication
  - Will not be used with another biologic or targeted synthetic drug for asthma, such as Xolair (omalizumab) or Cinqair (reslizumab)

- **EGPA**
  - Must have chart note documentation showing a beneficial response to treatment, as evidenced by either:
    - A reduction in the frequency of relapses
    - A reduction in the daily oral corticosteroid dose
    - No active vasculitis

- **HES**
  - Must have chart note documentation showing a beneficial response to treatment, as evidenced by a reduction in HES flares since starting treatment
  - Must have documentation or attestation from the provider that the requested medication is not being used as monotherapy

- **CRSwNP**
  - Must have chart note documentation showing a beneficial response to treatment, as evidenced by by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)
  - Must have documentation or attestation from the provider of the following:
    - That the member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated
    - Will not be used with another biologic or targeted synthetic drug for CRSwNP, such as Xolair (omalizumab)

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

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

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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].
8. GlaxoSmithKline. A Study to Investigate Mepolizumab in the Treatment of Eosinophilic Granulomatosis With Polyangiitis. Available from https://clinicaltrials.gov/ct2/show/record/NCT02020889. NLM identifier: NCT02020889. Accessed March 14, 2023.

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
Updated criteria for all indications and added indication-specific reauthorization criteria	09/24

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.

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