Mepolizumab (Nucala®) Vials	Place of Service Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Infusion Administration HCPCS: J2182 per 1 mg

Condition listed in policy *(see criteria for details)*

- Chronic rhinosinusitis with nasal polyps (CRSwNP)
- Eosinophilic granulomatosis with polyangiitis
- Hypereosinophilic syndrome
- Severe eosinophilic asthma

AHFS therapeutic class: Interleukin antagonists

Mechanism of action: Interleukin-5 antagonist monoclonal antibody

(1) Special Instructions and Pertinent Information

Nucala vials are managed under the Medical Benefit. Please submit clinical information for prior authorization review.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Nucala® (mepolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist, **AND**
2. Provider attestation that patient has nasal polyps, **AND**
3. Patient is ≥18 years of age, **AND**
4. Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid

Covered Dose
Up to 100 mg SC every 4 weeks

Coverage Period
Indefinite

ICD-10:
J32.9

Eosinophilic granulomatosis with polyangiitis (EGPA; formerly known as Churg-Strauss syndrome)

1. Patient is ≥ 18 years of age, **AND**
2. Prescribed by or in consultation with an immunologist, **AND**

3. Patient has relapsing or refractory disease despite treatment with oral corticosteroid and/or immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolic acid)

Covered Dose
Up to 300 mg (3 separate 100-mg injections) SC every 4 weeks

Coverage Period
Initial Authorization: 6 months
Reauthorization: Yearly if responding to and stable on treatment

ICD-10:
M30.1

Hypereosinophilic syndrome

1. Prescribed by or in consultation with an allergist or immunologist, **AND**
2. Patient is negative for FIP1-like 1-platelet derived growth factor receptor (FIP1L1-PDGFR) mutation, **AND**
3. Patient had an inadequate response to oral corticosteroids or hydroxyurea

Covered Dose
Up to 300 mg SC every 4 weeks

Coverage Period
Indefinite

ICD-10:
D72.11, D72.110, D72.111, D72.118, D72.119

Severe eosinophilic asthma

1. Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **AND**
2. Patient is at least 6 years of age, **AND**
3. Eosinophil blood count of ≥ 150 cells/µL within last 6 weeks or ≥ 300 cells/µL within the last 12 months, **AND**
4. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (LTRA), **AND**
5. Meets ONE of the following within the past year:
    - One or more acute asthma-related ED visit(s)
    - One or more acute inpatient visits where asthma was the principal diagnosis
    - Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

AND

6. Will not be used in combination with another biologic medication for asthma (e.g., Cinqair, Dupixent, Fasenra, and Xolair)

Covered Dose

Up to 100 mg SC every 4 weeks

Coverage Period
Initial Authorization: 6 months
Re-Authorization: Indefinite if the following criteria is met

1. Not used in combination with another biologic medication indicated for asthma treatment (e.g., Cinqair, Dupixent, Fasenra, and Xolair), AND
2. Provider attestation that asthma symptoms have improved and/or controlled while on Nucala

ICD-10:
J45.20-J45.998

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Nucala® (mepolizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)
Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 100 mg single-dose vial lyophilized powder (Administered by healthcare professional)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2022 Update). Available from: www.ginasthma.org.
- Nucala® (mepolizumab) [Prescribing Information]. Research Triangle Park, NC: GlaxoSmithKline; 10/2021.
- Wechsler ME, Akuthota P, Jayne D et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. N Engl J Med 2017;376:1921-32.

(7) Policy Update

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee