mepolizumab (Nucala) vials

Commercial Medical Benefit Drug Policy

Place of Service

Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: RESPIRATORY TRACT/PULMONARY AGENTS
Mechanism of Action: interleukin-5 (IL-5) antagonist monoclonal antibody that reduces the production and survival of eosinophils
HCPCS:
J2182:Injection, mepolizumab, 1 mg
How Supplied:
100 mg single-dose vial

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

- Severe Eosinophilic Asthma
- Chronic Obstructive Pulmonary Disease (COPD) - eosinophilic phenotype
- Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)
- Eosinophilic Granulomatosis with Polyangiitis (EGPA) - formerly known as Churg-Strauss Syndrome
- Hypereosinophilic Syndrome (HES)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Nucala vials are managed under the Medical Benefit. Please include medical rationale why medication cannot be home self-administered with the prefilled autoinjector or syringe. The prefilled autoinjector and syringe can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, and HMO (non-direct contract) may be required to have their medication administered

at a preferred site of service, including the home, a physicians' office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF NUCALA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (Supporting Documentation must be submitted)

1. Patient is receiving their first infusion of Nucala or is being re-initiated on Nucala after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Nucala based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Nucala based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Severe Eosinophilic Asthma

Meets medical necessity if all the following are met:

Initial

1. Age is consistent with the FDA-approved indication (6 years of age and older)
2. Eosinophil blood count of > 150 cells/µL
3. 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)
4. Meets ONE of the following within the past year:
   a. One or more acute asthma-related ED visit(s)
   b. One or more acute inpatient visits where asthma was the principal diagnosis
   c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids
5. Will not be used in combination with another biologic medication for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair, or Tezspire)
6. Dose does not exceed the FDA-approved maximum

Reauthorization
1. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment (e.g. Cinqair, Dupixent, Nucala, Xolair, Tezspire)
2. Asthma symptoms have improved or controlled while on Nucala
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Up to 100 mg given subcutaneously every 4 weeks

Coverage Period:
Initial: one year
Reauthorization: one year

ICD-10:
J45.20-J45.998

Chronic Obstructive Pulmonary Disease (COPD) - eosinophilic phenotype
Meets medical necessity if all the following are met:
Initial
1. Age is consistent with the FDA-approved indication (18 years of age and older)
2. Being prescribed by or in consultation with an allergist, immunologist or pulmonologist
3. Patient has moderate to very severe COPD (i.e., FEV1 <80% predicted) with an eosinophilic phenotype (i.e., blood eosinophil count ≥300 cells/uL)
4. One of the following (a or b):
    a. Being used as an add-on therapy in combination with a long-acting beta agonist (LABA), long-acting muscarinic antagonist (LAMA), and inhaled corticosteroid (ICS)
    b. Being used as an add-on therapy in combination with a LABA and LAMA in those who had an inadequate response, intolerable side effect, or contraindication to ICS
5. ***Effective 2/1/2026 and after***: Not being used in combination with other targeted immunomodulators for COPD
6. Dose does not exceed the FDA-approved maximum

Reauthorization
1. Patient's COPD symptoms (e.g., exacerbations) have improved while on Nucala
2. ***Effective 2/1/2026 and after***: Not being used in combination with other targeted immunomodulators for COPD
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Up to 100 mg given subcutaneously every 4 weeks

Coverage Period:
Initial: one year
Reauthorization: one year

ICD-10:
J44.0, J44.1, J44.81, J44.89, J44.9

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

Meets medical necessity if all the following are met:

Initial

1. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist
2. Patient has nasal polyps
3. Age is consistent with the FDA-approved indication (18 years of age and older)
4. Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid
5. ***Effective 2/1/2026 and after***: Not being used in combination with other targeted immunomodulators for CRSwNP
6. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient's symptoms improved while on Nucala
2. ***Effective 2/1/2026 and after***: Not being used in combination with other targeted immunomodulators for CRSwNP
3. Dose does not exceed the FDA-approved maximum

Covered Doses:

Up to 100 mg given subcutaneously every 4 weeks

Coverage Period:

Initial: one year

Reauthorization: one year

ICD-10:

J32.9

Eosinophilic Granulomatosis with Polyangiitis (EGPA) - formerly known as Churg-Strauss Syndrome

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (Patient is at least 18 years old)
2. Prescribed by or in consultation with an immunologist
3. ***Effective 2/1/2026 and after***: Not being used in combination with other targeted immunomodulators for EGPA
4. Patient has relapsing or refractory disease despite treatment with one of the following: (a or b)
   a. oral corticosteroid (e.g. prednisone, prednisolone)
   b. immunosuppressive therapy (e.g. azathioprine, methotrexate, mycophenolate mofetil)
5. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient is responding to Nucala
2. Not being used in combination with other targeted immunomodulators for EGPA
3. Dose does not exceed the FDA-approved maximum

Covered Doses:

Up to 300 mg given subcutaneously every 4 weeks

Coverage Period:

Initial: 6 months

Reauthorization: one year

ICD-10:

M30.1

Hypereosinophilic Syndrome (HES)
Meets medical necessity if all the following are met:
Initial
1. Age is consistent with the FDA-approved indication (Patient is at least 12 years of age)
2. Prescribed by or in consultation with an allergist or immunologist or hematologist
3. Patient is negative for FIP1-like 1-platelet derived growth factor receptor (FIP1L1-PDGFR) mutation
4. Patient had an inadequate response to oral corticosteroids or hydroxyurea
5. Dose does not exceed the FDA-approved maximum

Reauthorization
1. Patient's symptoms improved while on Nucala
2. Dose does not exceed the FDA-approved maximum

Covered Doses:
Up to 300 mg given subcutaneously every 4 weeks

Coverage Period:
Initial: one year
Reauthorization: one year

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

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2025 Update). Available from: www.ginasthma.org.
4. Nucala (mepolizumab) Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; 8/2025.
5. Wechsler ME, Akuthota P, Jayne D et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. N Engl J Med 2017; 376:1921-32.
6. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2025 report. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Bethesda, MD. 2025.

Review History

Date of Last Annual Review: 4Q2025
Changes from previous policy version:

- Severe eosinophilic asthma: Removed specialist requirement (Rationale: Prescribing patterns consistent with expected specialists)
- ***Effective 2/1/2026 and after:*** will require use not in combination with other targeted immunomodulators for CRSwNP, EGPA, and COPD. (Rationale: ensure appropriate use)

Reviewed by P&T Committee