mepolizumab (Nucala) vials

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 California Code of Regulations (CCR), Title 22, Section 51303 and 51313 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.

Coverage Criteria

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

Severe Eosinophilic Asthma

Meets medical necessity if all the following are met:

Initial

Blue Shield of California Promise Health Plan is an independent licensee of the Blue Shield Association

1. Age is consistent with the FDA-approved indication (6 years of age and older)
2. Eosinophil blood count of at least 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:
Not to exceed 100 mg given subcutaneously every 4 weeks

Coverage Period:
One year

ICD-10:
J45, J45.2, J45.20, J45.21, J45.22, J45.3, J45.30, J45.31, J45.32, J45.4, J45.40, J45.41, J45.42, J45.5, J45.50, J45.51, J45.52, J45.9, J45.90, J45.901, J45.902, J45.909, J45.99

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. Not being used in combination with other targeted immunomodulators for COPD(e.g. Dupixent)
6. Dose does not exceed the FDA-approved maximum

Reauthorization

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

Covered Doses:
Not to exceed 100 mg given subcutaneously every 4 weeks

Coverage Period:
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. Age is consistent with the FDA-approved indication (18 years of age and older)
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist
3. Patient has nasal polyps
4. Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid
5. Being used as add-on maintenance therapy
6. Not being used in combination with other targeted immunomodulators for CRSwNP (e.g. Dupixent, Xolair, Tezspire)
7. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient's symptoms improved while on Nucala
2. Not being used in combination with other targeted immunomodulators for CRSwNP (e.g. Dupixent, Xolair, Tezspire)
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Not to exceed 100 mg given subcutaneously every 4 weeks

Coverage Period:
One year

ICD-10:
J33.0, J33.1, J33.8, J33.9

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. Not being used in combination with other targeted immunomodulators for EGPA (e.g. Fasenra)
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 (eg. Fasenra)
3. Dose does not exceed the FDA-approved maximum

Covered Doses:

Not to exceed 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 cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, methotrexate)
5. ***Effective 11/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for HES (e.g., Fasenra)
6. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient's symptoms improved while on Nucala
2. ***Effective 11/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for HES (e.g., Fasenra)
3. Dose does not exceed the FDA-approved maximum

Covered Doses:
Not to exceed 300 mg given subcutaneously every 4 weeks

Coverage Period:
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:

- Clarified that use is not intended in combination with another therapy. (Rationale: Lack of adequate safety and efficacy data to support combination use of Nucala with Fasenra)

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee