# Pharmacy Medical Necessity Guidelines:
# Nucala (mepolizumab) Pre-filled Autoinjector and Syringe

*Effective: March 1, 2026*

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| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |
| These pharmacy medical necessity guidelines apply to the following:<br>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan | | **Fax Numbers:**<br>RXUM: 617.673.0939 | |

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**

Nucala (mepolizumab) is an interleukin-5 antagonist monoclonal antibody indicated:

- **Asthma**

As add-on maintenance treatment in patients with severe asthma aged 6 years and older with an eosinophilic phenotype

- **Chronic rhinosinusitis with nasal polyps**

As add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyps.

- **Eosinophilic granulomatosis with polyangiitis**

For the treatment of adults with eosinophilic granulomatosis with polyangiitis

- **Hypereosinophilic syndrome**

For the treatment of patient aged 12 years and older with hypereosinophilic syndrome for at least six (6) months without an identifiable non-hematologic secondary cause

## COVERAGE GUIDELINES

The plan may authorize coverage of Nucala pre-filled autoinjector and syringe for Members when **ALL** of the following criteria are met:

**Asthma**

Initial Authorization Criteria

1. Documented diagnosis of severe asthma of eosinophilic phenotype as determined by one of the following:
    a. An eosinophilic phenotype confirmed by a blood eosinophil level of at least 150 cells/mcL within the past six (6) weeks
    b. An eosinophilic phenotype confirmed by a blood eosinophil level of at least 300 cells/mcL within the past 12 months
    c. Current treatment with an alternative biologic indicated for moderate to severe allergic or eosinophilic asthma
    d. Patient is dependent on systemic corticosteroids

**AND**

2. Patient is at least 6 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

**AND**

4. Documentation the patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist)

**AND**

5. Documentation the patient will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of severe asthma of eosinophilic phenotype

**AND**

2. Patient is at least 6 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

**AND**

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Increase in percent predicted Forced Expiratory Volume (FEV1) from pretreatment baseline
    b. Reduction in the dose of inhaled corticosteroids required to control asthma
    c. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits)
    d. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)
    e. Reduction in the use of oral corticosteroids to treat and/or prevent asthma exacerbations

**AND**

5. Documentation the patient will not be concurrently treated with an alternative biologic for asthma

**Chronic Rhinosinusitis with Nasal Polyps**

Initial Authorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps as evidenced by both of the following:
    a. Symptoms of chronic rhinosinusitis for at least 12 weeks (e.g., decreased sense of smell; facial pressure, pain, fullness; mucopurulent drainage, mucosal inflammation, nasal obstruction)
    b. Presence of nasal polyps

**AND**

2. Patient is at least 18 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

**AND**

4. Documented of **one (1)** of the following:
    a. Patient will be concurrently treated with an intranasal corticosteroid
    b. Contraindication to intranasal corticosteroids

**AND**

5. Documentation the patient will not be concurrently treated with an alternative biologic for nasal polyps

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

**AND**

2. Patient is at least 18 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

**AND**

4. Documented of **one (1)** of the following:
    a. Patient is concurrently treatment intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

**AND**

5. Document the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbation

**AND**

6. Documentation the patient will not be concurrently treated with an alternative biologic for nasal polyps

**Eosinophilic granulomatosis with polyangiitis**

Initial Authorization Criteria

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

**AND**

2. Patient is at least 18 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist

**AND**

4. Documentation of **one (1)** of the following:
    a. The patient is stable on corticosteroids
    b. Contraindication to corticosteroids

**AND**

5. Documentation the patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

Reauthorization Criteria

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

**AND**

2. Patient is at least 18 years of age or older

**AND**

3. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist

**AND**

4. Documentation the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. A reduction in the frequency and/or severity of relapses
    b. A reduction or discontinuation of doses of corticosteroids
    c. Disease remission

**Hypereosinophilic Syndrome**

1. Documented diagnosis of hypereosinophilic syndrome

**AND**

2. Documentation that non-hematologic secondary causes (e.g., parasitic, allergic) have been ruled out

**AND**

3. Documentation of a blood eosinophil count of at least 1,000 cells/mcL prior to the start of treatment

**AND**

4. Patient is at least 12 years of age or older

**AND**

5. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, dermatologist, or gastroenterologist

**AND**

6. Documentation of **one (1)** of the following:
    a. Trial and failure with at least one (1) of the following: An oral corticosteroid, oral immunosuppressant, or cytotoxic therapeutic agent
    b. Contraindication to all of the following: Oral corticosteroids, oral immunosuppressants, and cytotoxic therapies

## LIMITATIONS

- For the treatment of severe asthma, chronic rhinosinusitis with nasal polyps, and eosinophilic granulomatosis with polyangiitis, initial coverage of Nucala will be authorized for six (6) months. Reauthorization of Nucala for asthma, chronic rhinosinusitis with nasal polyps, and eosinophilic granulomatosis with polyangiitis will be provided in 12-month intervals.
- Patients new to the plan stable on Nucala should be reviewed against Reauthorization Criteria.

## CODES

None

## REFERENCES


1. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; August 2025.
2. Bergmark RW, Pynnonen M. Diagnosis and First-Line Treatment of Chronic Sinusitis. JAMA 2017; 318:2344.
3. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg 2015; 152:S1
4. National Heart, Lung, and Blood Institute (NHLBI) & National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group (EPR-4). 2020. Accessed April 17, 2024.
5. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention - GINA Report Updated 2023. 2023. Accessed April 17, 2024
6. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014 Feb; 43(2):343-373.
7. Chun EJ, Zhang HP, Lv Yan, et al. The Asthma Control Test and Asthma Control Questionnaire for assessing asthma control: systemic review and meta -analysis. J Allergy Clin Immunol. 2013 Mar;131(3):695-703.


## APPROVAL HISTORY

September 13, 2023: Reviewed by Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- May 14, 2024: For asthma, added the patient is dependent on systemic corticosteroids as an option to determine the documented diagnosis of severe asthma of eosinophilic phenotype. For chronic rhinosinusitis with nasal polyps removed documentation the patient remains symptomatic despite treatment with an intranasal corticosteroid or contraindication to intranasal corticosteroids, and removed documentation of prior treatment with systemic corticosteroids, contraindication to systemic corticosteroids or previous nasal polyps (eff 6/1/2024).
- May 13, 2025: No changes (eff 5/13/25).
- February 10, 2026: For EGPA, removed documentation the patient has at least two (2) disease characteristics of EGPA (eff 3/1/26).

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.