MVP Health Care Medical Policy

Medicare Part B: Select Immunomodulating Agents

Type of Policy: **Drug Therapy**
Prior Approval Date: **06/01/2025**
Approval Date: **08/01/2026**
Effective Date: **04/01/2026**
Related Policies: **Medicare Part B: Xolair**

Drug Requiring Prior Authorization (covered under the medical benefit)

J2182 Nucala® (Injection, mepolizumab, 1mg)
J2786 Cinqair® (Injection, reslizumab,1mg)
J0517 Fasenra® (Injection, benralizumab,1mg) auto injector

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

Refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available

Overview/Summary of Evidence

The medications listed in this policy are indicated to treat a range of diagnoses include asthma, eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyps, hypereosinophilic syndrome (HES).

Indications/Criteria:

Medications identified in this policy that are self-administered fall under the Medicare Part D (pharmacy) benefit. Refer to the MVP website for the Medicare Part D formulary and prior authorization criteria for drugs that may covered under the Part D benefit.

A. ASTHMA

Nucala, Cinqair and Fasenra:

Nucala, Cinqair, or Fasenra may be considered for coverage for asthma when the following **drug specific criteria** are met:

- For Nucala and Fasenra
    - Member must have a documented diagnosis of severe eosinophilic asthma with one of the following:
    - A peripheral blood eosinophil count of at least 150 cells/microliter **OR**
    - Member is dependent on systemic corticosteroids
- For Cinqair:
    - Must have a peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days OR
    - Member is dependent on systemic corticosteroids

Nucala, Cinqair, or Fasenra may be considered for coverage for asthma when the following criteria is met in addition to the specific drug criteria above:

- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription claim history must identify that the member is compliant with the use of a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA)
- Member still experiencing poor asthma control and has had at least two asthma exacerbations in the previous year
    - Poor asthma controlled defined as limitations of physical activity or exacerbations affecting activities of daily living
    - Exacerbations must have required treatment with systemic corticosteroids, hospitalization, or an emergency room visit
- Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks
- Documentation that other medical and environmental conditions known to exacerbate asthma have been evaluated and treated
- Provider administered medications under the medical benefit may be considered for coverage if the following is provided:
    - Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**

- Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy.

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in asthma symptoms and exacerbations.

B. Eosinophilic Granulomatosis with Polyangiitis

Nucala or Fasenra will be considered for coverage for Eosinophilic Granulomatosis with Polyangiitis when all the following are met:

- Member has a documented diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) for at least 6 months confirmed by presence of:
  - Asthma plus eosinophilia (>1.0x10^9/Liter and/or >10% of leucocytes) plus at least two of the following additional features of EGPA
    - A biopsy confirming eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    - Neuropathy
    - Pulmonary infiltrates
    - Sino-nasal abnormality
    - Cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage
    - Palpable purpura
    - Anti neutrophil cytoplasmic anti-body (ANCA) positive.

- Documentation of relapsing or refractory disease defined as:
  - Failure with an adequate trial of corticosteroid therapy
- Documented failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine).

Provider administered medications under the medical benefit may be considered for coverage when:

- Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**
- Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy

Initial approval will be for 6 months.

Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations

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C. Chronic Rhinosinusitis with Nasal Polyps

Nucala will be considered for coverage for Chronic Rhinosinusitis nasal polyps when all the following are met:

- Confirmed diagnosis of nasal polyps. Chart notes must document diagnosis confirmation by examination, endoscopy or sinus computed tomography (CT) scan.
- Prescribed by or in consultation with an allergist, otolaryngologist or immunologist
- Documented trial and failure of three (3) months, to at least one intranasal corticosteroid indicated to treat nasal polyps.
- Documented failure, contraindication, intolerance, or allergy to other therapy used in the management of nasal polyps such as nasal saline irrigations, or antileukotriene agents (montelukast, zafirlukast, zileuton).
- Documentation of prior oral corticosteroid therapy and/or sinus surgery
- Nucala will be add on maintenance in combination with an intranasal corticosteroid

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to 12 months will be based upon a positive clinical response.

D. Hypereosinophilic Syndrome

Nucala and Fasenra will be considered for coverage of Hypereosinophilic Syndrome when all the following are met:

- Prescribed by or in consultation with an allergist or immunologist
- Member has a documented diagnosis of hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause
- Documentation of baseline eosinophil count and previous HES flares

Initial approval will be for 6 months.

Continued authorization must be accompanied by current chart notes identifying continued benefit. Extension of therapy for up to 12 months will be based upon a positive clinical response including a decrease in HES flares as well as documentation of decreasing eosinophil count from baseline.

E. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype

Nucala will be considered for the coverage of adults **inadequately controlled** chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype when all of the following are met:

- Confirmed diagnosis of COPD
- Member is followed by an allergist, immunologist or pulmonologist
- Member has eosinophilic phenotype with eosinophil count ≥300 cells/microliter
- Documentation of inadequate control with combination therapy (either double or triple therapy) consisting of an inhaled corticosteroid (ICS), long-acting beta agonist (LABA), or long-acting muscarinic antagonist (LAMA)
- Provider attestation that Nucala will be add on maintenance treatment

Provider administered medications under the medical benefit may be considered for coverage when:

- Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**
- Member has coverage under Medicare Part B and meets the criteria for a provider administered drug identified in this policy

Initial approval will be for 12 months

Continued authorization for up to 12 months will be considered if there is a documented decrease in symptoms and exacerbations, continued eosinophilic phenotype, and ongoing adherence to maintenance therapy

Exclusions

- For hypereosinophilic syndrome (HES):
    - Members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling
- Dual therapy with another monoclonal antibody that is not supported by current clinical guidelines
- Treatment of acute bronchospasm or status asthmaticus

References

1. Ortega H, Liu MC, Pavord I, et al. Mepolizumab Treatment in Patients with Severe Eosinophilic Asthma. N Engl J Med 2014; 371:1198-1207
2. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. August 2007. Available at: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2016. Available from www.ginasthma.org
4. Nucala (mepolizumab) for injection. Prescribing Information. Philadelphia, PA. GlaxoSmith Kline LLC. Revised 08/2025.
5. Cinqair (reslizumab) injection. Prescribing Information. West Chester, PA. Teva Respiratory LLC. Revised 02/2020.
6. Wechsler ME, Akuthota P, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932.
7. Prescribing Information. Fasenra (benralizumab) subcutaneous injection Wilmington, DE. Astra Zeneca. Revised 09/2024.
8. Global Strategy for Asthma Management and Prevention. 2023 Update. GINA Main Report 2023 Front Cover (ginasthma.org). 2023 GINA Main Report - Global Initiative for Asthma - GINA
9. Keating MK, Phillips JC, Phillips J. Chronic Rhinosinusitis. Am Fam Physician. 2023 Oct;108(4):370-377. PMID: 37843944.