MVP Health Care Medical Policy

Medicare Part B: Select Injectables for Asthma

Type of Policy:	**Drug Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**11/01/2023**
Effective Date:	**01/01/2024**
Related Policies:	**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)

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

Overview/Summary of Evidence

Asthma is a chronic inflammatory disease of the airways. Asthma affects between 1-18% of the population. Nucala, Cinqair, and Fasenra are interleukin-5 antagonist monoclonal antibodies indicated for add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is also indicated for adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

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:

- Must have a diagnosis of severe eosinophilic asthma with one of the following:
    - A peripheral blood eosinophil count of at least 150 cells/microliter
    - For Cinqair: Must have a peripheral blood eosinophil count of at least 400 cells/microliter in the past 30 days

- Member must be followed by an allergist, immunologist or pulmonologist
- Documentation and prescription 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
- Other medical and environmental conditions know to exacerbate asthma must be maximally treated
- Nucala IV and Fasenra syringe may be considered for coverage if the following is provided:
    a) Rationale and documentation are provided identifying why the member or caregiver is unable to self-administer **OR**
    b) 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 will be considered for coverage when all the following are met:

- Must have a 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 antibody (ANCA) positive.

- Relapsing or refractory disease defined as:
    - Failure with an adequate trial of corticosteroid therapy
- Failure with at least one adequate trial of immunosuppressive therapy (i.e. azathioprine, methotrexate, mycophenolate, cyclosporine). Nucala IV will be considered for coverage if rationale and documentation is 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.

C. Nasal Polyps

Nucala will be considered for coverage when all the following are met:

- Confirmed diagnosis of nasal polyps
- Documented failure, contraindication, intolerance or allergy to at least one intranasal corticosteroid indicated to treat nasal polyps.
- **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 one year will be based upon a positive clinical response.

D. Hypereosinophilic Syndrome

Nucala will be considered for coverage when all the following are met:

- Prescribed by or in consultation with an allergist or immunologist
- Member as 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 one year will be based upon a positive clinical response including a decrease in HES

flares as well as documentation of decreasing eosinophil count from baseline.

Exclusions

- Nucala
    1. For hypereosinophilic syndrome (HES): members with non-hematologic secondary HES or FIP1L1-PDGFRα kinase positive HES
- Dose and age limits outside FDA approved indications
- Combination use of Nucala, Cinqair, Fasenra or Xolair
- Cinqair given more frequently than every 4 weeks
- Use of Fasenra or Cinqair for the treatment of other eosinophilic conditions
- Diagnosed with granulomatosis with polyangiitis (GPA; previously known as Wegener's granulomatosis) or microscopic polyangiitis (MPA).

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. October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf
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.March 2023.
5. Cinqair (reslizumab) injection. Prescribing Information. Frazer, PA. Teva Respiratory LLC.February 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. February 2021.GINA 2023 - Global Strategy for Asthma Management and Prevention (ginasthma.org)