# New Hampshire Medicaid Fee-for-Service Program

# Asthma/Allergy Immunomodulator Criteria

**Approval Date: January 22, 2024**

## Indications

| Generic Name (Brand Name) | Mechanism of Action | Indications |
|---|---|---|
| **benralizumab (Fasenra®)** | interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1 kappa) | • Add-on maintenance treatment of patients with severe asthma who are ≥ 12 years old with an eosinophilic phenotype. |
| **mepolizumab (Nucala®)** | interleukin-5 antagonist monoclonal antibody (IgG1 kappa) | • Add-on maintenance treatment of patients with severe asthma who are ≥ 6 years old with an eosinophilic phenotype<br>• Treatment of adults with eosinophilic granulomatosis with polyangiitis<br>• Treatment of hypereosinophilic syndrome lasting ≥ 6 months without an identifiable non-hematologic secondary cause in patients ≥ 12 years of age<br>• Add-on maintenance treatment of adults with chronic rhinosinusitis with nasal polyps and an inadequate response to nasal corticosteroids |
| **omalizumab (Xolair®)** | anti-IgE antibody | • Moderate to severe persistent asthma in patients ≥ 6 years old inadequately controlled with inhaled corticosteroids<br>• Chronic spontaneous urticaria in patients ≥ 12 years old who are symptomatic despite h1 antihistamine treatment<br>• Maintenance treatment of chronic rhinosinusitis with nasal polyps in adults who have an inadequate response to nasal corticosteroids |
| **reslizumab (Cinqair®)** | interleukin-5 antagonist monoclonal antibody (IgG1 kappa) | • Add-on maintenance treatment of patients with severe asthma ≥ 18 years old with an eosinophilic phenotype |
| **tezepelumab-ekko (Tezspire™)** | thymic stromal lymphopoietin (TSLP) inhibitor | • Add-on maintenance treatment of patients with severe asthma who are ≥ 12 years old |

## Medications

| Brand Names | Generic Names | Dosage Forms |
|---|---|---|
| **Fasenra®** | benralizumab | 30 mg/mL single-dose prefilled syringe (HCP); 30 mg/mL prefilled single-dose autoinjector (self-administered) |
| **Nucala®** | mepolizumab | 100 mg powder for reconstitution, 100 mg/1 mL single-dose prefilled autoinjector and single-dose prefilled syringe |
| **Xolair®** | omalizumab | 150 mg/1.2 mL vial, 75 mg/0.5 mL and 150 mg/1 mL single-dose prefilled syringe |
| **Cinqair®** | reslizumab | 100 mg/10 mL vial |
| **Tezspire™** | tezepelumab-ekko | 210 mg/1.91 mL single-dose prefilled syringe, vial, pen |

**For requests for dupilumab (Dupixent®), use the Dupixent® criteria.**

## Criteria for Approval

1. Prescriber is an allergist, immunologist, or pulmonologist (or one of these specialists has been consulted); **AND**
2. Diagnosis of chronic spontaneous urticaria (for Xolair® only); **AND**
   a. Patient is ≥ 12 years of age; **AND**
   b. Patient has had an inadequate response to first or second generation H1-antihistamine; **OR**
3. Diagnosis of eosinophilic granulomatosis with polyangiitis (for Nucala® only); **AND**
   a. Patient is ≥ 18 years of age; **OR**
4. Diagnosis of hypereosinophilic syndrome with no identifiable non-hematologic secondary cause lasting ≥ 6 months (for Nucala® only); **AND**
   a. Patient is ≥ 12 years of age; **OR**
5. Diagnosis of chronic rhinosinusitis with nasal polyps (for Nucala® and Xolair® only); **AND**
   a. Patient is ≥ 18 years of age; **AND**
   b. Patient has had an inadequate response to nasal corticosteroids; **OR**
6. Diagnosis of moderate (for Xolair® only) or severe, persistent asthma; **AND**
   a. Patient is ≥ 6 years of age (Xolair® and Nucala®);
   b. Patient is ≥ 12 years of age (Fasenra® and Tezspire™);
   c. Patient is ≥ 18 years of age (Cinqair®); **AND**
7. Inadequately controlled asthma despite medium-to-high doses of corticosteroid (inhaled or oral) in combination with:
   a. Long-acting beta agonist; **OR**
   b. Leukotriene receptor agonist; **OR**

c. Theophylline; **AND**

8. History of positive skin test or *in vitro* test to perennial aeroallergen or eosinophilic phenotype (not required for Tezspire™); **AND**
9. Non-smoker status.

Non-Preferred drugs on the preferred drug list (PDL) require additional PA.

## Length of Authorization

Initial six months, extended approval for 12 months if additional criteria are met.

## Criteria for 12-month Renewal

1. Approved for initial six-month trial; **AND**
2. Clinical improvement was seen.

## Criteria for Denial

1. Above criteria are not met; **OR**
2. If being used for peanut allergy only; **OR**
3. Patient is an active smoker; **OR**
4. Failure to be compliant with current regimen as evidenced by review of claims history; **OR**
5. For asthma diagnosis only, no claims history of inhaled corticosteroid, long-acting beta agonist, leukotriene receptor, antagonists, or theophylline in the last 120 days for new prescriptions only.

## References

Available upon request.

## Revision History

| Reviewed by | Reason for Review | Date Approved |
|---|---|---|
| Pharmacy & Therapeutic Committee | New | 09/05/2006 |
| Commissioner | Approval | 09/29/2006 |
| Pharmacy & Therapeutic Committee | Update | 04/19/2009 |
| Commissioner | Approval | 05/12/2009 |
| DUR Board | Update | 10/19/2011 |
| Commissioner | Approval | 04/12/2012 |
| DUR Board | Update | 05/31/2016 |
| Commissioner | Approval | 06/18/2016 |
| DUR Board | Update | 09/27/2018 |
| Commissioner Designee | Approval | 11/27/2018 |
| DUR Board | Update | 03/12/2019 |
| Commissioner Designee | Approval | 04/05/2019 |
| DUR Board | Update | 10/28/2019 |
| Commissioner Designee | Approval | 12/03/2019 |
| DUR Board | Update | 06/30/2020 |
| Commissioner Designee | Approval | 08/07/2020 |
| DUR Board | Update | 06/08/2021 |
| Commissioner Designee | Approval | 08/13/2021 |
| DUR Board | Revision | 06/02/2022 |
| Commissioner Designee | Approval | 07/12/2022 |
| DUR Board | Revision | 12/08/2023 |
| Commissioner Designee | Approval | 01/22/2024 |