New Hampshire Medicaid Fee-for-Service Program
Asthma/Allergy Immunomodulator Criteria

Approval Date: June 10, 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 ≥ 6 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 • Treatment of adults with eosinophilic granulomatosis with polyangiitis • Treatment of hypereosinophilic syndrome lasting ≥ 6 months without an identifiable non-hematologic secondary cause in patients ≥ 12 years of age • 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 • Chronic spontaneous urticaria in patients ≥ 12 years old who are symptomatic despite h1 antihistamine treatment • Maintenance treatment of chronic rhinosinusitis with nasal polyps in adults who have an inadequate response to nasal corticosteroids • Reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy
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

Generic Name (Brand Name)	Mechanism of Action	Indications
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	10 mg/0.5mL single-dose prefilled syringe; 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, 150 mg/1 mL, and 300 mg/2 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**
   - Patient is 12 years of age or older; **AND**
   - 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**
   - Patient is 18 years of age or older; **OR**
4. Diagnosis of hypereosinophilic syndrome with no identifiable non-hematologic secondary cause lasting 6 months or longer (for Nucala only); **AND**
   - Patient is 12 years of age or older; **OR**
5. Diagnosis of chronic rhinosinusitis with nasal polyps (for Nucala and Xolair only); **AND**
   - Patient is 18 years of age or older; **AND**
   - Patient has had an inadequate response to nasal corticosteroids; **OR**
6. Diagnosis of IgE-mediated food allergy (for Xolair only); **OR**

7. Diagnosis of moderate (for Xolair only) or severe, persistent asthma; **AND**
   - Patient is 6 years of age or older (Fasenra, Xolair and Nucala);
   - Patient is 12 years of age or older (Tezspire);
   - Patient is 18 years of age or older (Cinqair); **AND**
8. Inadequately controlled asthma despite medium-to-high doses of corticosteroid (inhaled or oral) in combination with:
   - Long-acting beta agonist; **OR**
   - Leukotriene receptor agonist; **OR**
   - Theophylline; **AND**
9. History of positive skin test or *in vitro* test to perennial aeroallergen or eosinophilic phenotype (not required for Tezspire); **AND**
10. Non-smoker status (asthma only).

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. Failure to be compliant with current regimen as evidenced by review of claims history; **OR**
3. 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; **OR**
4. For asthma diagnosis only, patient is an active smoker.

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
DUR Board	Revision	05/07/2024
Commissioner Designee	Approval	06/10/2024