

Injectable Immunomodulators Criteria

Revised: 02/25/2025

INJECTABLE IMMUNOMODULATORS CRITERIA

Length of Authorization: Initial – 1 year
Renewal – 1 year

CRITERIA TO APPROVE

Chart notes and documentation of the following:

Dupixent

- **Add-on maintenance treatment of moderate to severe asthma diagnosed as one of the following types:**
 - Asthma with eosinophilic phenotype with eosinophil count \geq 150 cells/mcL; **OR**
 - Oral corticosteroid dependent asthma with at least one month of daily oral corticosteroid use within the last three months.
 - Patient \geq 6 years of age
 - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
 - Patient’s asthma symptoms have not been adequately controlled by at least three months of an asthma treatment regimen that must include an inhaled corticosteroid
- **Add-on maintenance treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP):**
 - Patient \geq 12 years of age
 - **One** of the following:
 - Inadequate response to intranasal steroids or oral corticosteroids after 3 consistent months of use
 - Intolerance or contraindication to intranasal steroids or oral corticosteroids
 - Patient is concurrently treated with intranasal corticosteroids
- **Diagnosis of eosinophilic esophagitis (EoE):**
 - Patient \geq 1 year of age
 - Weight \geq 15 kg
 - Prescribed by or consultation with an allergist or gastroenterologist
 - No clinical response to treatment with a topical glucocorticosteroid or proton pump inhibitor (PPI)
- **Diagnosis prurigo nodularis (PN):**
 - Patient \geq 18 years of age
 - Prescribed by or in consultation with a dermatologist, allergist, or immunologist
- **Add-on maintenance treatment of chronic obstructive pulmonary disease (COPD) with lung function classified by GOLD Grade 2 or 3 (FEV-1% predicted between 30–70%)**
 - Patient \geq 18 years of age

- Prescribed by or consultation with a pulmonologist
- Blood eosinophil count ≥ 300 cells/ μ L
- Patient is receiving maximal inhaled therapy for a minimum of 3 months (LAMA/LABA/ICS or LAMA/LABA if ICS is contraindicated)
- Patient is inadequately controlled, defined by:
 - **Two** moderate exacerbations (oral corticosteroid or antibiotic required)
 - **One** severe exacerbation (hospitalization or ER visit)

Xolair

- **Diagnosis of moderate to severe asthma:**
 - Patient ≥ 6 years of age
 - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
 - Patient has a positive skin test or in vitro testing (e.g., RAST) for allergen specific IgE antibodies for one or more seasonal aeroallergens
 - Baseline IgE level ≥ 30 IU/mL
 - Patient's asthma symptoms have not been adequately controlled by at least three months of an asthma treatment regimen that must include an inhaled corticosteroid
- **Diagnosis of chronic spontaneous urticaria:**
 - Patient ≥ 12 years of age
 - Prescribed by or in consultation with an allergist, immunologist, or dermatologist
 - Patient has had urticaria for at least 6 weeks with symptoms present, despite an adherent trial of at least 2 weeks duration of an H1-antihistamine (e.g., cetirizine, levocetirizine, desloratadine, loratadine, fexofenadine, chlorpheniramine, diphenhydramine)
- **Diagnosis of chronic rhinosinusitis with nasal polyps:**
 - Patient ≥ 18 years of age
 - Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist
 - Patient has not been adequately controlled by at least three months of treatment with an intranasal corticosteroid or oral corticosteroids
 - Patient is concurrently treated with intranasal corticosteroids
- **Diagnosis of IgE-mediated food allergy:**
 - Patient ≥ 1 year of age
 - Prescribed by or in consultation with an allergist or immunologist
 - Patient will follow food allergen avoidance in conjunction with Xolair

Fasenra

- **Add-on maintenance treatment of severe asthma (eosinophilic type):**
 - Patient ≥ 6 years of age
 - Prescribed by or in consultation with an allergist, immunologist, or pulmonologist
 - Eosinophil blood count ≥ 150 cells/ μ L within last six weeks or ≥ 300 cells/ μ L within the last 12 months
 - Patient's asthma symptoms have not been adequately controlled by at least three months of an asthma treatment regimen that must include an inhaled corticosteroid

- **Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA):**
 - Patient ≥ 18 years of age

CONTINUATION OF THERAPY

- The patient has had a positive response to therapy; **AND**
- Patient has not experienced any treatment-restricting adverse effects.

REVISION HISTORY

Date	Issues/Updates
02/25/2025	• Initial draft creation