

Xolair® (omalizumab)

When requesting Xolair® (omalizumab), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

- Xolair® (omalizumab) is indicated for:
 - The treatment of moderate to severe persistent asthma in individuals with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
 - The treatment of chronic idiopathic urticarial in individuals who remain symptomatic despite treatment with a histamine-1 (H1) antihistamine.

Approved Off-label Compendial use

- The treatment of allergic rhinitis, seasonal or perennial, in individuals with a positive skin test or in vitro reactivity for one or more relevant allergens who remain symptomatic despite treatment with standard therapy.

Coverage Guidelines

Asthma in Patients with Moderate to Severe Persistent Disease

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 6 years of age or older
- Xolair must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Patient has a baseline IgE level of greater than or equal to 30 IU/mL
- The patient has a baseline positive skin test or in vitro testing for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens
- Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND
 - o At least ONE of the following:
 - Inhaled long-acting beta agonist (LABA) [e.g., Serevent Diskus]; OR
 - Inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; OR
 - Leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; OR

- Theophylline
- NOTE: Use of a combination inhaler containing both ICS and a LABA would fulfill the requirement.
- **EXCEPTION** to the requirement for a trial to one additional asthma controller/maintenance medication is if the patient already has been receiving anti-IL-4/13 therapy (Dupixent) in combination with an ICS for at least 3 consecutive months.
- Patient's asthma is uncontrolled defined by ONE of the following:
 - o The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o The patient experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
 - o Patient has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Patient has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o The patient's asthma worsens upon tapering of oral corticosteroids therapy

Approval duration: 4 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 4 months of therapy with Xolair (NOTE: Patients who have received less than 4 months of therapy or those who are restarting therapy with Xolair should be considered under initial criteria)
- Patient continues to receive therapy with one inhaled corticosteroid (ICS) or on ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- The patient has responded to Xolair therapy as determined by the prescribing physician (e.g., decreased asthma symptoms or exacerbations; decreased hospitalizations, emergency room visits, or physician visits due to asthma; decreased reliever/rescue medication use; increase lung function parameters)

Approval duration: 12 months

Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria)

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 12 years of age or older
- Xolair must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist

- Patient has/had urticarial for greater than 6 weeks, with symptoms present for greater than 3 days per week despite daily non-sedating H1 antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) with doses that have been titrated up to a maximum of four times the standard FDA-approved dose

Approval duration: 4 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 4 months of therapy with Xolair (NOTE: Patients who have received less than 4 months of therapy or those who are restarting therapy with Xolair should be considered under initial criteria)
- The patient has responded to Xolair therapy as determined by the prescribing physician (e.g., decreased severity of itching, decreased number and/or size of hives)

Approval duration: 12 months

Allergic Rhinitis, Seasonal or Perennial

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 12 years of age or older
- Xolair must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Patient has a baseline IgE level of greater than or equal to 30 IU/mL
- Patient has seasonal or perennial allergic rhinitis as demonstrated by baseline positive skin testing and/or baseline positive in vitro testing for one or more relevant allergens
- Patient has tried therapy with at least one drug from TWO of the following groups of drugs at the same time:
 - o Oral second-generation/less-sedating antihistamines (e.g., cetirizine, fexofenadine, or loratadine); OR
 - o Intranasal antihistamines (e.g., azelastine nasal spray [Astepro, generics] or olopatadine nasal spray [Patanase, generics]; OR
 - o Intranasal corticosteroids (e.g., fluticasone); OR
 - o Montelukast
- Patient meets one of the following:
 - o Patient has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy; OR
 - o There is no immunotherapy available for the allergen identified as causing the clinically significant allergy; OR

- o The patient has contraindication to immunotherapy (e.g., patients receiving beta blockers or patients with medical conditions that reduce their ability to survive a systemic allergic reaction [e.g., markedly compromised lung function, poorly controlled asthma, unstable angina, recent myocardial infarction or significant dysrhythmia, uncontrolled hypertension, failure of a major organ system such as renal failure])

Approval duration: 4 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 4 months of therapy with Xolair (NOTE: Patients who have received less than 4 months of therapy or those who are restarting therapy with Xolair should be considered under initial criteria)
- The patient has responded to Xolair therapy as determined by the prescribing physician (e.g., decreased symptoms of sneezing; itchy nose; watery, red, or itchy eyes; itchy throat; nasal congestion)

Approval duration: 12 months

Dosing Guidelines

Asthma: Dose is determined based on pre-treatment serum IgE and patient body weight. Refer to the prescribing information for specific dosing recommendations. The maximum dose is 375 mg given subcutaneously once every 2 weeks.

Urticaria: The maximum recommended dose is 300 mg given subcutaneously once every 4 weeks.

Allergic Rhinitis:

- For adults, the dose must meet one of the following:
 - o The dose is 300 mg given subcutaneously once every 3 to 4 weeks; OR
 - o The dose is at least 0.016 mg/kg/IgE (units/mL) subcutaneously once every 4 weeks; OR
- For adolescents, the dose is at least 0.016 mg/kg/IgE (units/mL) subcutaneously once every 4 weeks.

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