

Xolair® (omalizumab)

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

FDA-Approved Indications

Asthma

Xolair is indicated for patients 6 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Chronic Idiopathic Urticaria

Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

Approved Off-label Compendial Use

Allergic rhinitis

Coverage Guidelines

Moderate to Severe Persistent Asthma

Initial authorization:

- The individual must meet **all** of the following criteria approval: Has a baseline immunoglobulin E (IgE) level of greater than or equal to 30 IU/mL
- Has a baseline positive skin test or in vitro test (i.e., a blood test) for allergen-specific IgE for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens
- Has received at least 3 consecutive months of following combination therapy:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND an anti-interleukin-4/13 therapy (i.e. Dupixent)

OR

 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND at least one additional asthma controller/maintenance medication (e.g., inhaled long-acting beta₂ agonist (LABA) [e.g., Serevent Diskus]; inhaled long-acting muscarinic antagonist

(LAMA) [e.g., Spiriva]; leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; theophylline)

OR

- o A combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂ agonist (e.g., Symbicort, Advair, Dulera)
- Asthma is uncontrolled defined by ONE of the following:
 - o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o Has experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
 - o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o Asthma worsens upon tapering of oral corticosteroids therapy
- Is 6 years of age or older
- Xolair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Reauthorization:

The individual must meet **all** of the following criteria for approval:

- Has already received at least 4 months of Xolair therapy (*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*)
- Continues to receive therapy with one inhaled corticosteroid (ICS) or on ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- Has responded to Xolair therapy (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)

Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria)

Initial authorization:

The individual must meet **all** of the following criteria for approval:

- Has/had urticaria for greater than 6 weeks, with symptoms present for more 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
- Is 12 years of age or older

- Xolair is prescribed by or in consultation with an allergist, immunologist, or dermatologist

Reauthorization:

The patient must meet **all** of the following criteria for approval:

- Has already received at least 4 months of Xolair therapy (*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*)
- Has responded to Xolair therapy (e.g., decreased severity of itching, decreased number and/or size of hives)

Allergic Rhinitis

Initial authorization:

The individual must meet **all** of the following criteria for approval:

- Has a baseline IgE level of greater than or equal to 30 IU/mL
- Has a baseline positive skin test or in vitro test (i.e., a blood test) for allergen-specific IgE for one or more perennial aeroallergens AND/OR for one or more seasonal aeroallergens
- Has tried at least one drug from TWO of the following groups of drugs at the same time:
 - o Oral second-generation/non-sedating antihistamines (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, 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
- Meets one of the following:
 - o Has had immunotherapy, is receiving immunotherapy, or will be receiving immunotherapy; OR
 - o There is no immunotherapy available for the allergen identified as causing clinically significant allergy; OR
 - o Has contraindication to immunotherapy (e.g., receiving beta blockers or has 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])
- Is 12 years of age or older
- Xolair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Reauthorization:

The individual must meet **all** of the following criteria for approval:

- Has already received at least 4 months of Xolair therapy (*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*)
- Has responded to Xolair therapy (e.g., decreased symptoms of sneezing, itchy nose, watery/red/itchy eyes, itchy throat, or nasal congestion)

Approval duration (initial): 4 months

Approval duration (renewal): 12 months

Dosing Guidelines

Asthma

The recommended dose of Xolair is 75 mg to 375 mg administered subcutaneously every 2 or 4 weeks.

Urticaria

The recommended dose of Xolair is 150 mg or 300 mg administered subcutaneously every 4 weeks.

References

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