



## MVP Health Care Medical Policy

---

### Medicare Part B: Xolair® (omalizumab)

<b>Type of Policy:</b>	<b>Medical Therapy (<i>administered by the pharmacy department</i>)</b>
<b>Prior Approval Date:</b>	<b>N/A</b>
<b>Approval Date:</b>	<b>11/01/2023</b>
<b>Effective Date:</b>	<b>01/01/2024</b>
<b>Related Policies:</b>	<b>NA</b>

---

### Drugs Requiring Prior Authorization (covered under the medical benefit)

J2357 Xolair® (omalizumab)

Refer to the Medicare Part D formulary for drugs that may be covered under the Part D benefit.

---

### Overview/Summary of Evidence

Omalizumab (Xolair®) is a recombinant DNA-derived humanized IgG1k monoclonal antibody that selectively binds to human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor (FcεRI) on the surface of mast cells and basophils and reduces the number of FcεRI receptors on basophils. It is administered once or twice a month, with dosing based on the member's weight and IgE level. Xolair inhibits inflammation at its source versus suppressing inflammation once it has occurred. Symptom improvement is seen by four weeks from the start of treatment.

The Food and Drug Administration (FDA) reports that serious and life-threatening anaphylactic reactions have occurred in patients after treatment with Xolair®. Usually, these reactions occur within two hours of receiving a Xolair subcutaneous injection. However, new reports include patients who had delayed anaphylaxis—with onset two to 24 hours or even longer after receiving Xolair treatment. Anaphylaxis may occur after *any* dose of Xolair (including the first dose), even if the patient had no allergic reaction to the first dose. The symptoms and signs of anaphylaxis in these reported patients include bronchospasm, hypotension, syncope, urticaria, and angioedema of the throat or tongue. Health care professionals who administer Xolair should be prepared to manage life-threatening anaphylaxis and should observe their Xolair-treated patients for at least two hours after the drug is given. Patients under treatment with Xolair should be

fully informed about the signs and symptoms of anaphylaxis, their chance of developing delayed anaphylaxis following Xolair treatment, and how to treat it when it occurs.

---

## Indications/Criteria

Xolair (omalizumab) is FDA approved for:

- Subcutaneous injection in adults and pediatric 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 in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Nasal polyps in adults' patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment

### **A. Treatment with Xolair for ALL indications will be considered when the following criteria is met. Please see section B for indication specific criteria.**

- Patients must meet age requirements based on the FDA approved labeling for the applicable FDA approved indicated. **AND**
- Patient must meet the criteria below for the treatment for moderate to severe persistent asthma OR chronic idiopathic urticaria OR nasal polyps. Self-administration of Xolair is a Medicare Part D benefit and follows the Medicare Part D Prior Authorization criteria requirements.

### **B. Treatment for Xolair will be considered for the following indications:**

#### **1. For moderate to severe persistent asthma:**

- a. The NHLBI Expert Panel recommends that omalizumab may be considered as adjunctive therapy in step 5 or 6 care for patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose ICS and LABA.
- b. Documentation by the prescriber must meet the following criteria:
  - Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months
  - NIH-NHLBI classification of severe persistent asthma, for > 1 year, with claims history and/or medical chart documentation of all the following:
    1. Continual or daily symptoms (daytime or nighttime)

2. Limited physical activity or exacerbations affecting activities of daily living (ADL's)
  3. Frequent exacerbations or exacerbations at least 2 times a week which may last days
  4. FEV<sub>1</sub> or PEF ≤80% predicted
  5. PEF variability >30%
  6. Increasing use of short acting beta2 agonist or use >2 days/week for symptom relief
- c. Evidence of compliance with:
- High dose Inhaled Corticosteroids (ICS) required for daily control
  - Inadequate control on combination therapy (moderate dose ICS and a Long-Acting Beta-Agonist, formoterol OR ICS and Long-Acting Muscarinic Antagonist as an alternative) for at least 6 months
  - Oral Corticosteroid use of at least two courses within the past 12 months for asthmatic exacerbations or the inability to wean from systemic corticosteroids
- d. Specific relevant allergic sensitivities to perennial aeroallergens (dust mites, mold, animal dander, cockroaches, etc.) determined by:
- Skin tests or
  - *In vitro* testing
- e. Use in accordance with product literature or supporting clinical documentation for consideration on a case-by-case basis when outside published dosing limits:
- Baseline IgE level (>30 IU/ml and ≤700 IU/ml)
  - Body Weight (≤150 kg)
- f. Be a non-smoker by history or have a successful smoking cessation for at least 6 weeks.

**Initial authorization** for a 3-month trial to evaluate outcomes and responses to therapy.

- **Extension of therapy** up to 12 months clinical documentation showing a positive clinical response must be identified

**2. For chronic idiopathic urticaria:**

- a. Documentation by the prescriber must meet the following criteria:

- Requests must be submitted by a participating plan allergist, immunologist, or pulmonologist who has managed the patient for at least six months
- Urticaria is persistent or recurring over 6 weeks in duration; **AND**
- Individual lesions of urticaria lasting less than 24 hours (if longer than 24 hours then urticarial vasculitis must first be ruled out, which may include ESR, complement assays, and biopsy); **AND**
- Other causes for urticaria (such as occupational, insect sting/bite, medications, food, infection, physical sensitivity) has been ruled out; **AND**
- Patient has remained symptomatic despite:
  - At least a two-week trial of a maximally tolerated dose of a potent H1 antihistamine (such as Hydroxyzine or Doxepin) in combination with one of the following:
    - Another Second Generation H1 antihistamine
    - H2 antihistamine
    - First-generation H1 antihistamine at night
    - Leukotriene receptor antagonist

**Initial authorization** for a 3-month trial to evaluate outcomes and responses to therapy.

**Extension of therapy** up to 12 months based on improvement in chronic idiopathic urticaria on Xolair therapy. Improvement in chronic idiopathic urticaria includes but is not limited to a decrease in itching or a decrease in hive count.

### 3. For nasal polyps

- a. The use of Xolair may be considered medically necessary if all the following criteria are met:
  - Confirmed diagnosis of nasal polyps
  - Documented failure, contraindication, intolerance, or allergy to at least one intranasal corticosteroid indicated to treat nasal polyps

**Initial coverage** will be for 3 months.

**Requests for continuation** of therapy must be accompanied by current chart notes identifying a continued benefit. Extension of therapy for up to one year will be based upon a positive clinical response.

## Exclusions

### When used for moderate to severe persistent asthma:

- current smokers
- a diagnosis other than allergic asthma, including allergic rhinitis, other allergic conditions, non-allergic asthma, allergic bronchopulmonary aspergillosis
- current treatment has not been optimized using applicable alternatives such as
  1. high dose inhaled corticosteroids (ICS)
  2. leukotriene modifiers or theophylline if preferred therapies (ICS, LABA/LAMA) are not appropriate.
  3. long-acting beta agonists
  4. allergy injections (immunotherapy)
  5. member compliance
  6. inhaler technique
  7. environmental controls
- omalizumab (Xolair) is not indicated for the treatment of acute bronchospasm or status asthmaticus
- other medical and environmental conditions known to exacerbate asthma have not been evaluated and treated.
- Combination use with other biologics (e.g., Cinqair, Dupixent, Fasentra, Nucala)

### When used for chronic idiopathic urticaria:

- a diagnosis other than chronic idiopathic urticaria
- omalizumab (Xolair) is not indicated for acute urticaria, urticarial vasculitis, or urticaria with a known cause

---

## References

1. Xolair<sup>®</sup> (omalizumab). Prescribing Information. South San Francisco, CA: Genentech Inc.;2014 Mar.
2. U.S. Department of Health and Human Services (2002). Expert panel report: guidelines for the diagnosis and management of asthma: update on selected topics 2002. National Asthma Education and Prevention Program.
3. U.S. Department of Health and Human Services (2003). Key clinical activities for quality asthma care: recommendation of the national asthma education and prevention program. National Asthma Education and Prevention Program.
4. Rosenwasser, L.J. & Nash, D.B. (2003). Incorporating omalizumab into asthma treatment guidelines: consensus panel recommendations. P&T 28(6) 400-10.
5. US Food and Drug Administration Alert (February 2007) online at [www.fda.gov](http://www.fda.gov)

6. National Asthma Education and Prevention Program. Guidelines for the diagnosis and management of asthma: expert panel report 3. Bethesda, Md.: U.S. Dept. of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute, 2007; NIH publication no. 08-5846.
7. National Government Services, Inc. Article for omalizumab (e.g., Xolair) – Related to LCD L25820 (A46088). Original Article Effective Date 12/01/2007. Article Revision Effective Date 6/5/2009. Available: <http://www.ngsmedicare.com>
8. Joint Task Force on Practice Parameters. The diagnosis and management of acute and chronic urticaria: a 2014 update. *J Allergy Clin Immunol* 2014; 133 (5): 1270-77.
9. Schaefer P. Urticaria: Evaluation and Treatment. *Am Fam Physician*. 2011;83(9):1078-84.
10. [2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group | NHLBI, NIH](#)
11. [Acute and Chronic Urticaria: Evaluation and Treatment - American Family Physician \(aafp.org\)](#)
12. [A Comparison of the United States and International Perspective on Chronic Urticaria&nbsp;Guidelines \(jaci-inpractice.org\)](#)