

**omalizumab (Xolair)****Medical Benefit Drug Policy**Place of Service

Home Infusion

Infusion Center Administration

Office Administration

Outpatient Facility Infusion Administration

Self-Administration *(may be covered by your Pharmacy Benefit)***Drug Details****USP Category:** IMMUNOLOGICAL AGENTS**Mechanism of Action:** Recombinant DNA-derived humanized IgG1 monoclonal antibody**HCPCS:**

J2357:Injection, omalizumab, 5 mg

**How Supplied:**

75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL solution in a single-dose prefilled syringe

75 mg/0.5 mL, 150 mg/mL and 300 mg/2 mL solution in a single-dose prefilled autoinjector

150 mg lyophilized powder in a single-dose vial

**Condition(s) listed in policy** *(see coverage criteria for details)*

- Allergic Asthma, moderate to severe persistent
- Chronic Rhinosinusitis with Nasal Polyps
- Chronic Spontaneous Urticaria (CSU)
- Immunoglobulin E (IgE)-Mediated Food Allergy
- Immunotherapy-Related Pruritus
- Systemic Mastocytosis

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the California Code of Regulations (CCR), Title 22, Section 51303 and 51313 must be met.

**Special Instructions and Pertinent Information**

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

## Coverage Criteria

The following condition(s) require Prior Authorization/Preservice.

### Allergic Asthma, moderate to severe persistent

Meets medical necessity if all the following are met:

#### Initial

1. Patient has moderate to severe persistent allergic asthma
2. Patient is at least 6 years of age
3. Total serum IgE level is  $\geq 30$  IU/ml and the pre-treatment IgE levels do not exceed manufacturer's dosing recommendations (see Additional Information section)
4. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (LTRA)
5. Meets ONE of the following within the past year:
  - a. One or more acute asthma-related ED visit(s)
  - b. One or more acute inpatient visits where asthma was the principal diagnosis
  - c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids
6. Will not be used in combination with another biologic medication for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)
7. Dose does not exceed the FDA-approved maximum

#### Reauthorization

1. Not used in combination with another biologic medication indicated for asthma treatment (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)
2. Asthma symptoms have improved and/or controlled while on Xolair
3. Dose does not exceed the FDA-approved maximum

#### **Covered Doses:**

75 to 375 mg given as a subcutaneous injection every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts in Additional Information section.

#### **Coverage Period:**

Initial: 24 weeks or 6 months

Reauthorization: Yearly

#### **ICD-10:**

J45.40, J45.41, J45.42, J45.50, J45.51, J45.52, J45.901, J45.902, J45.909, J45.998

### Chronic Rhinosinusitis with Nasal Polyps

Meets medical necessity if all the following are met:

### Initial

1. Prescribed or recommended by an allergist, immunologist, or otolaryngologist
2. Patient is at least 18 years of age
3. Patient has nasal polyps
4. Inadequate response, intolerable side effect, or contraindication to intranasal glucocorticoid
5. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for CRSwNP
6. Dose does not exceed the FDA-approved maximum

### Reauthorization

1. Patient's symptoms improved while on Xolair
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for CRSwNP
3. Dose does not exceed the FDA-approved maximum

### **Covered Doses:**

Up to 600 mg given as a subcutaneous injection every 2 to 4 weeks

### **Coverage Period:**

Initial: 6 months

Reauthorization: Yearly, based on continued response to therapy

### **ICD-10:**

J32.9

### **Chronic Spontaneous Urticaria (CSU)**

**Meets medical necessity if all the following are met:**

#### Initial

1. Age is consistent with the FDA-approved indication
2. Inadequate response or intolerance after titration up to the maximally tolerated dose of a second-generation antihistamine (2-4 times FDA approved dose), or contraindication to second-generation antihistamines
3. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for CSU
4. Dose does not exceed the FDA-approved maximum

#### Reauthorization

1. Patient is responding to therapy
2. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for CSU
3. Dose does not exceed the FDA-approved maximum

**Covered Doses:**

300 mg given as a subcutaneous injection every 4 weeks

**Coverage Period:**

Initial: 6 months

Reauthorization: Yearly, based on continued response to therapy

**ICD-10:**

L50.1

**Immunoglobulin E (IgE)-Mediated Food Allergy****Meets medical necessity if all the following are met:**

1. Diagnosis of IgE-mediated food allergy as demonstrated by positive skin prick test (SPT), serum IgE, or food challenge to one or more foods (e.g., peanut, milk, egg, wheat, cashew, hazelnut, walnut)
2. Being prescribed by or in consultation with an allergist or immunologist
3. Being used in conjunction with food allergen avoidance
4. ***Effective 2/1/2026 and after:*** Total serum IgE level is  $\geq 30$  IU/mL and the pre-treatment IgE levels do not exceed manufacturer's dosing recommendations

**Covered Doses:**

75 mg to 600 mg given as a subcutaneous injection every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See the dose determination charts in Additional Information Section.

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

J30.5, L27.2, T78.00XA, T78.00XD, T78.00XS, T78.01XA, T78.01XD, T78.01XS, T78.02XA, T78.02XD, T78.02XS, T78.03XA, T78.03XD, T78.03XS, T78.04XA, T78.04XD, T78.04XS, T78.05XA, T78.05XD, T78.05XS, T78.06XA, T78.06XD, T78.06XS, T78.07XA, T78.07XD, T78.07XS, T78.08XA, T78.1XXA, T78.1XXD, T78.1XXS, Z91.010, Z91.011, Z91.012, Z91.013, Z91.014, Z91.018

**Immunotherapy-Related Pruritus****Meets medical necessity if all the following are met:**

1. Prescribed by or in consultation with a dermatologist, allergist, immunologist, hematologist, or oncologist
2. Patient has severe pruritus due to immune checkpoint inhibitor therapy (i.e., PD-1/PD-L1 inhibitors, CTLA-4 inhibitor)
3. Patient has increased IgE levels

4. Being used for refractory disease

**Covered Doses:**

Up to 300 mg given as a subcutaneous injection every 4 weeks

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

L29.8, L29.9

**Systemic Mastocytosis**

**Meets medical necessity if all the following are met:**

1. One of the following:
  - a. Used for prevention of anaphylaxis
  - b. Used to improve tolerance while on venom immunotherapy
  - c. Used as prophylactic treatment for chronic mast cell mediator-related cardiovascular (e.g., pre-syncope, tachycardia) or pulmonary (e.g., wheezing, throat swelling) symptoms, AND both of the following:
    - i. Inadequate response or intolerable side effect with an antihistamine, or contraindication to all antihistamines
    - ii. Inadequate response or intolerable side effect with a corticosteroid, or contraindication to all corticosteroids

**Covered Doses:**

Up to 150 mg given as a subcutaneous injection every 2 weeks or 300 mg given as a subcutaneous injection every 4 weeks

**Coverage Period:**

Yearly, based on continued response to therapy

**ICD-10:**

C94.30, C94.31, C94.32, C96.20, C96.21, C96.22, C96.29, D47.02

**Additional Information**

**IgE-Mediated Food Allergy**

- Xolair is given subcutaneously every 2 or 4 Weeks for patients 1 year of age and older
- Dosing should be adjusted during therapy for significant changes in actual body weight. Dosing should not be adjusted based on total IgE levels taken during treatment or <1 year following interruption of therapy. If therapy has been interrupted for  $\geq 1$  year, total IgE levels may be reevaluated for dosage determination. Periodically reassess the need for continued therapy; appropriate duration of therapy has not been evaluated.

**References**

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14. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA<sup>2</sup>LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022; 77: 734–766.

## Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Allergic asthma: Removed specialist requirement (Rationale: Prescribing patterns consistent with expected specialists)

- Immunoglobulin E (IgE)-mediated food allergy: ***Effective 2/1/2026 and after***, will require IgE level is  $\geq 30$  IU/mL and that pre-treatment IgE levels not exceed manufacturer's dosing recommendations (Rationale: Xolair prescribing information)
- CSU and CRSwNP: ***Effective 2/1/2026 and after***, will require use not in combination with other targeted immunomodulators for CSU and CRSwNP. (Rationale: Ensure appropriate use)

*Blue Shield of California Medication Policy to Determine Medical Necessity  
Reviewed by P&T Committee*