

## omalizumab (Xolair)

### Commercial 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 Health and Safety Code section 1367.21 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.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Members with the following plans: PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct) may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION**

*MCG Care Guidelines, 19th edition, 2015*

ADMINISTRATION OF THIS DRUG IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted*)

1. Patient is starting new therapy with this drug (allowed for first month). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
2. Patient is being re-initiated on this drug after being off therapy for at least 6 months (allowed for first month). Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.
3. Additional clinical monitoring is required during administration as evidenced by one of the following:
  - a. Patient has experienced a previous severe adverse event on this drug based on documentation submitted.
  - b. Patient continues to experience moderate to severe adverse events on this drug based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
  - c. Patient is clinically unstable based on documentation submitted.
  - d. Patient is physically or cognitively unstable based on documentation submitted

**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 at least 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, Fasentra, Nucala, Tezspire)

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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). Dose determination charts can be found in the drug's prescribing information.

**Coverage Period:**

Initial: one year

Reauthorization: one year

**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. Being used as add-on maintenance therapy
6. Not being used in combination with other targeted immunomodulators for CRSwNP (e.g., Dupixent, Nucala, Tezspire)
7. Dose does not exceed the FDA-approved maximum

Reauthorization

1. Patient's symptoms improved while on Xolair
2. Not being used in combination with other targeted immunomodulators for CRSwNP (e.g., Dupixent, Nucala, Tezspire)
3. Dose does not exceed the FDA-approved maximum

**Covered Doses:**

Not to exceed 600 mg given as a subcutaneous injection every 2 to 4 weeks

**Coverage Period:**

Initial: one year

Reauthorization: one year

**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 (12 years of age or older)
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. Not being used in combination with other targeted immunomodulators for CSU (e.g., Dupixent, Rhapsido)
4. Dose does not exceed the FDA-approved maximum

### Reauthorization

1. Patient is responding to therapy
2. Not being used in combination with other targeted immunomodulators for CSU (e.g. Dupixent, Rhapsido)
3. Dose does not exceed the FDA-approved maximum

### **Covered Doses:**

Not to exceed 300 mg given as a subcutaneous injection every 4 weeks

### **Coverage Period:**

Initial: 6 months

Reauthorization: Yearly

### **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. 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). Dose determination charts can be found in the drug's prescribing information.

### **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,

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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:**

Not to exceed 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:**

Not to exceed 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

### **References**

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## Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- For chronic rhinosinusitis with nasal polyps (CRSwNP): clarify use as add-on maintenance therapy. Rationale: Prescribing information
- Clarification of initial coverage period for asthma and CRSwNP to 1 year

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