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 initiating on Xolair (allow for first month) or is being re-initiated on Xolair after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Xolair based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Xolair based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. 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 ≥ 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 ≥ 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 ≥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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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 ≥ 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