Omalizumab (Xolair®)	<u>Place of Service</u> Office Administration Home Infusion Administration Infusion Center Administration Outpatient Facility Administration Self-Administration *(may be covered by Pharmacy Benefit)* **HCPCS: J2357** per 5 mg

Conditions listed in policy (*see criteria for details*)
- Chronic idiopathic urticaria
- Chronic rhinosinusitis with nasal polyps
- Immunotherapy-related pruritus
- Moderate to severe persistent allergic asthma
- Systemic mastocytosis

AHFS therapeutic class: Respiratory Tract Agents, Miscellaneous

Mechanism of action: recombinant DNA-derived humanized IgG1 monoclonal antibody that selectively binds to human immunoglobulin E (IgE)

(1) Special Instructions and Pertinent Information

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review.

Xolair syringes under the outpatient Pharmacy Benefit for self-administration. After the member has initiated therapy in a healthcare setting and the provider determines that self-administration is appropriate, the member can request Xolair syringes from their Pharmacy Benefit. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

**CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION **

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, Medi-Cal, and when applicable, ASO/Shared Advantage/HMO (non-direct contract)** 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.

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

1. **Patient is receiving their first two infusions of Xolair 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.**

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Xolair® (omalizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Chronic idiopathic urticaria

1. Diagnosis of moderate to severe chronic idiopathic urticaria, **AND**
2. Prescribed by an allergist or immunologist, **AND**
3. Patient is 12 years of age or older, **AND**
4. A history of (a) or (b) or (c):
    a. Inadequate response to a one-week trial of hydroxyzine or doxepin, or
    b. Inadequate response or intolerance after titration up (2-4 times FDA approved dose) to the maximally tolerated dose of a second-generation antihistamine, or
    c. Intolerance or contraindication to hydroxyzine, doxepin and second-generation antihistamines.

Covered Doses
Up to 300 mg subcutaneous injection every 4 weeks

Coverage Period
Initial: 6 months
Reauthorization: Indefinite if responded to therapy

ICD-10:
L50.1

Chronic rhinosinusitis with nasal polyps

1. Prescribed or recommended by an allergist, immunologist, or otolaryngologist, **AND**
2. Provider attestation that patient has nasal polyps, **AND**
3. Patient is at least 18 years of age, **AND**
4. Inadequate response, intolerable side effect, or contraindication to intranasal glucocorticoid

Covered Dose
Up to 600 mg subcutaneous injection every 2 to 4 weeks

Coverage Period
Initial: 6 months
Reauthorization: Indefinite if responded to therapy

ICD-10:
J32.9

Immunotherapy-related pruritus

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

Covered Dose
Up to 300 mg subcutaneous injection every 4 weeks

Coverage Period
Yearly

ICD-10:
L29.8, L29.9

Moderate to severe persistent allergic asthma

1. Patient has moderate to severe persistent allergic asthma, **AND**
2. Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **AND**
3. Patient is at least 6 years of age, **AND**
4. Total serum IgE level is ≥ 30 IU/ml and the pre-treatment IgE levels do not exceed manufacturer's dosing recommendations (see tables below), **AND**
5. 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), **AND**
6. Meets ONE of the following within the past year:
    a. One or more acute asthma-related ED visit(s) (verify against claim history when possible), OR
    b. One or more acute inpatient visits where asthma was the principal diagnosis (verify against history or charting), OR
    c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids

    AND
7. Will not be used in combination with another biologic medication for asthma (e.g., Cinqair, Dupixent, Fasenra, and Nucala)

Covered Doses
See tables

Age 6 to <12 yrs:
Every 2 or 4 weeks for pediatric patients who begin Xolair between the ages of 6 to <12 years

Pre-treatment Serum IgE (IU/ml)	Dosing Freq.	Body Weight (kg)									
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
		Dose (mg)									
≥ 30-100	Every 4 Weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 Weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375					DO NOT DOSE		
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Age >12 yrs: Baseline Serum IgE 700-1500 IU/ml
Maximum of 600 mg subcutaneous injection every 2 to 4 weeks

Age >12 yrs: Serum IgE 30-700 IU/ml
Maximum of 375 mg subcutaneous injection every 2 to 4 weeks per the charts below:

Doses Every 4 Weeks for Patients 12 Years of Age and Older with Asthma

Pre-Treatment serum IgE (IU/ml)	Body Weight (kg) 30-60	>60-70	>70-90	>90-150
≥ 30-100	150	150	150	300
>100-200	300	300	300	
>200-300	300			
>300-400				
>400-500		See Table Below		
>500-600				
>600-700				

Doses Every 2 Weeks for Patients 12 Years of Age and Older with Asthma

Pre-Treatment serum IgE (IU/ml)	Body Weight (kg) 30-60	>60-70	>70-90	>90-150
≥ 30-100		See Table Above		
>100-200				225
>200-300		225	225	300
>300-400	225	225	300	
>400-500	300	300	375	
>500-600	300	375		
>600-700	375		Do Not Dose	

Coverage Period

Initial Approval: 24 weeks or 6 months

Reauthorization - Indefinite if all of the following are met:

1. Not used in combination with another biologic medication indicated for asthma treatment (e.g., Cinqair, Dupixent, Fasenra, and Nucala), AND
2. Provider attestation that asthma symptoms have improved and/or controlled while on Xolair

ICD-10:

J45.20, J45.30, J45.40, J45.50, J45.21, J45.22, J45.31, J45.32, J45.41, J45.42, J45.51, J45.52, J45.901, J45.902, J45.909, J45.998

Systemic mastocytosis

1. One of the following:
   a. Used for prevention of anaphylaxis, or
   b. Used to improve tolerance while on venom immunotherapy, or
   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, and
      ii. Inadequate response or intolerable side effect with a corticosteroid, or contraindication to all corticosteroids

Covered Dose

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

Coverage Period

Indefinite

ICD-10:

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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Xolair® (omalizumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 150 mg (single-dose vial)

- 75 mg (single-dose prefilled syringe)
- 150 mg (single-dose prefilled syringe)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Bernstein JA, Lang DM, Khan DA et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol 2014.133(5);1270-7.

- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. J Allergy Clin Immunol. 2020;146(6):1217-1270.
- Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2022 Update). Available from: www.ginasthma.org.
- Kornmann O, Watz H, Fuhr R, et al. Omalizumab in patients with allergic (IgE-mediated) asthma and IgE/bodyweight combinations above those in the initially approved dosing table. Pulmonary Pharmacology and Therapeutics 2014;28:149-53.
- Maselli DJ, Singh H, Diaz J, et al. Efficacy of omalizumab in asthmatic patients with IgE levels above 700 IU/mL: a retrospective study. Annals of Allergy, Asthma & Immunology 2013;110:457-61.
- Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med 2013;368(10):924-935.
- Xolair (omalizumab) [Prescribing Information]. South San Francisco, CA: Genentech. 7/2021.
- Xolair. National Comprehensive Cancer Network Drugs & Biologics Compendium (2022). Available by subscription at: www.nccn.org.
- Zielen S, Lieb A, De La Motte S, et al. Omalizumab Protects against Allergen-Induced Bronchoconstriction in Allergic (Immunoglobulin E-Mediated) Asthma. International Archives of Allergy and Immunology 2013;160:102-10.
- Zuberbier T, Aberer W, Asero R et al. The EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. Allergy 2018;73(7):1393-1414.

(7) Policy Update

Date of last review: 1Q2023

Date of next review: 1Q2024

Changes from previous policy version:

- No clinical change to policy following routine annual review.