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:Omalizumab injection
How Supplied:

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

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

- Chronic idiopathic urticaria
- Chronic rhinosinusitis with nasal polyps
- Immunotherapy-related pruritus
- Moderate to severe persistent allergic asthma
- 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.
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 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:

1. **Patient has experienced a previous severe adverse event on Xolair based on documentation submitted.**
2. **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.**
3. **Patient is clinically unstable based on documentation submitted.**
4. **Patient is physically or cognitively unstable based on documentation submitted.**

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

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 (see below), or
   c. Intolerance or contraindication to hydroxyzine, doxepin and second-generation antihistamines.

Covered Doses:

300 mg given by subcutaneous injection every 4 weeks

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

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

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

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
4. **Effective 4/29/2024 and after**: Being used for refractory disease

Covered Doses:
300 mg given as a subcutaneous injection every 4 weeks

Coverage Period:
Yearly

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), OR

b. One or more acute inpatient visits where asthma was the principal diagnosis, 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:

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							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

DO NOT DOSE

Age >12 yrs: Baseline Serum IgE 700-1500 IU/ml

600 mg given by subcutaneous injection every 2 to 4 weeks

Age >12 yrs: Serum IgE 30-700 IU/ml

375 mg given by subcutaneous injection every 2 to 4 weeks per the charts below:

Dose 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				

Dose 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: 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

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 Doses:
150 mg given by subcutaneous injection every 2 weeks or 300 mg given by subcutaneous injection every 4 weeks

Coverage Period:
Indefinite

References

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Review History

Date of Last Annual Review: 1Q2024
Date of last revision: 02/28/2024
Changes from previous policy version:

- Immunotherapy-related pruritus: ***Effective 4/29/2024***, will require disease to be refractory for coverage. *Rationale: NCCN category 2A support*

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