CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Xolair (omalizumab)
BENEFIT TYPE	Medical or Pharmacy

Xolair (omalizumab) was initially approved by the FDA in 2003 for the treatment of moderate-to-severe persistent asthma. Xolair was the first monoclonal antibody approved for the treatment of asthma. It has gained additional indication approvals for the treatment of chronic spontaneous urticaria, for the add-on maintenance treatment of adults with nasal polyps, and IgE-mediated food allergy.

Xolair (omalizumab) will be considered for coverage when the following criteria are met:

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with allergist, immunologist, or otorhinolaryngologist (ENT); AND
3. Member has a diagnosis of bilateral CRSwNP for more than 12 weeks; AND
4. Chart notes must show documentation of bilateral nasal polyps by direct examination, endoscopy, or sinus CT scan; AND
5. The member's weight (kg) and baseline serum IgE level (IU/mL) are documented in chart notes; AND
6. Member has symptoms of chronic rhinosinusitis after at least a 4-week trial with an intranasal corticosteroid (e.g., mometasone, fluticasone) in combination with nasal saline irrigation; AND
7. Member has **ONE** of the following:
   a) Prior sinonasal surgery;
   b) Trial of systemic corticosteroids (unless not tolerated or contraindicated); AND
8. Medication is used as an add-on maintenance treatment in combination with intranasal corticosteroid; AND
9. Medication is **NOT** used in combination with other biologic therapies for CRSwNP.
10. **Dosage allowed/Quantity limit:** 75 mg to 600 mg subQ every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and body weight (kg). See the dose determination chart in package insert.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Medication is to be used as add-on maintenance therapy in combination with intranasal corticosteroids; AND
2. Chart notes have been provided showing improvement of signs and symptoms such as reduced post-nasal drip, reduced nasal polyp size, and/or reduced nasal congestion symptoms.

If all the above requirements are met, the medication will be approved for an additional 12 months.

Chronic Spontaneous Urticaria (CSU)

For **initial** authorization:

1. Member is at least 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of an allergist, dermatologist, or immunologist; AND
3. Member has a diagnosis of moderate to severe chronic spontaneous urticaria, with the appearance of wheals, angioedema, or both, that has been present for more than 6 weeks; AND
4. Member has trialed and failed a second generation H1 antihistamine (i.e. loratadine, cetirizine, fexofenadine) at 2-4 times the FDA-approved dosage for 14 days; AND
5. Member will continue to use a second generation H1 antihistamine with Xolair.
6. **Dosage allowed/Quantity limit:** 150 or 300 mg by subcutaneous injection every 4 weeks.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes have been provided to support a positive clinical response (i.e. reduction in itch severity and/or hive count).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Moderate to Severe Persistent Asthma

For **initial** authorization:

1. Member is at least 6 years of age or older; AND
2. Medication must be prescribed by on in consultation with an allergist, immunologist, or pulmonologist; AND
3. Member has allergy testing performed, as indicated by:
   a) Positive skin testing for perennial aeroallergen; OR
   b) Reactivity to at least one aeroallergen documented by elevated serum IgE level; AND
4. Member has a weight documented and a baseline plasma immunoglobulin E (IgE) level of 30 IU/mL or higher; AND
5. Member has at least **TWO** documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least **ONE** requiring hospitalization, within last year; AND
6. Member's asthma has been inadequately controlled after 3 months of conventional treatment of medium to high doses of inhaled corticosteroids (ICS) and long-acting beta 2-agonists (LABA); AND
7. Medication is being used as add-on maintenance treatment to conventional therapies for asthma (i.e. ICS, LABA, etc.); AND
8. Medication is **NOT** used in conjunction with any other biologic therapy for asthma.
9. **Dosage allowed/Quantity limit:** 75 to 375 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and body weight (kg). See the dose determination chart in package insert.

If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Medication is **NOT** being used as monotherapy for asthma; AND
2. Chart notes have been provided that show the member has demonstrated improvement by **ONE** of the following:
   a) Decreased frequency of emergency department visits or hospitalizations due to asthma exacerbations; OR
   b) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   c) Decreased utilization of rescue medications or oral corticosteroids.

If all the above requirements are met, the medication will be approved for an additional 12 months

IgE-mediated Food Allergy

For **initial** authorization:

1. Member is at least 1 year of age or older; AND
2. Medication must be prescribed by on in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of IgE-mediated food allergy confirmed by clinical history of allergic reactions;
4. Chart notes document positive skin prick test OR positive serum IgE; AND
5. The member's weight (kg) and baseline serum IgE level (IU/mL) are documented in chart notes; AND
6. Provider attests medication will be used concomitantly with food allergen avoidance; AND
7. Medication will **NOT** be used with Palforzia.
8. **Dosage allowed/Quantity limit:** 75 mg to 600 mg SC every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and body weight (kg). See the dose determination chart in package insert.

If all the above requirements are met, the medication will be approved for 16 weeks .

For **reauthorization**:

1. Provider attests medication will continue to be used with food allergen avoidance; AND
2. Chart notes have been provided to show the member is clinically benefiting from therapy and has **NOT** had anaphylaxis requiring advanced medical care.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Xolair (omalizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
05/18/2017	New policy for Xolair created. For CIU urticaria activity score, trial of oral corticosteroids and trial length added.
01/12/2021	Persistent Asthma: added documented weight; added exacerbation requirement (two requiring OCS or one requiring hospitalization within the last year); FEV1 removed; ICS + LTRA removed; added not to be used with other asthma biologics. CIU: added immunologist; documented urticaria activity and itch severity scores removed; trial of oral corticosteroids removed; added trial option of a 2nd generation H1antihistamine 2-4x FDA approved dosage; added examples of trial drugs for reference. New indication Nasal Polyps added.
02/24/2022	Transferred to new template. Annual review; no changes
05/03/2024	Added pharmacy benefit option for self-administration. Added/removed references. Added IgE-mediated food allergy diagnosis. Asthma: clarified dosing to reference package insert. CRSwNP: removed that member does not have allergic fungal rhinosinusitis, added that medication will not be used with other biologics. CSU: changed indication name from chronic idiopathic urticaria to chronic spontaneous urticaria per labeled indication and change in nomenclature; simplified

	trials per guidelines; lengthened initial approval from 14 weeks to 6 months; added that member will take Xolair with a second generation H1 antihistamine; removed that CSU has been continuous or intermittent and replaced with guidelines definition of spontaneous appearance of wheals, angioedema, or both

References:

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