Xolair (omalizumab) is a preferred product and will only be considered for coverage under the medical benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

**CHRONIC RHINOSINUSITIS WITH NASAL POLYPOsis (CRSwNP)**

For **initial** authorization:
1. Member is 18 years old 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. 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 one of the following:
   a) Prior sinonasal surgery;
   b) Systemic corticosteroids (unless not tolerated or contraindicated); AND
6. Medication is used as an add-on maintenance treatment in combination with intranasal corticosteroid, unless not tolerated or contraindicated; AND
7. The member’s weight (kg) and baseline serum IgE level (IU/mL) is documented in chart notes; AND
8. Member does not have allergic fungal rhinosinusitis (AFRS).
9. **Dosage allowed:** 75 mg to 600 mg subQ every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight (kg). See the dose determination chart in package insert.

*If member meets all the requirements listed above, the medication will be approved for 6 months.*

For **reauthorization**:
1. Member must be in compliance with all other initial criteria; AND
2. Medication is to be used as add-on maintenance therapy in combination with intranasal corticosteroids, unless not tolerated or contraindicated; AND
3. 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*
**CHRONIC IDIOPATHIC URTICARIA (CIU)**

For initial authorization:
1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a dermatologist, allergist, or immunologist; AND
3. Member has a diagnosis of Chronic Idiopathic Urticaria that has been continuously or intermittently present for at least 6 weeks; AND
4. Member has trialed and failed at least one of the following for no less than 14 days:
   a) A second generation H1 antihistamine (i.e. loratadine, cetirizine, fexofenadine) at 2-4 times the FDA-approved dosage;
   b) Two second generation H1 antihistamines in combination;
   c) A second generation H1 antihistamine plus a leukotriene receptor antagonist (i.e. montelukast, zafirlukast);
   d) A second generation H1 antihistamine plus a first generation H1 antihistamine (i.e. diphenhydramine, hydroxyzine, chlorpheniramine);
   e) A second generation H1 antihistamine plus an H2 antagonist (i.e. famotidine, cimetidine, ranitidine).
5. **Dosage allowed:** 150 or 300 mg by subcutaneous injection every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For reauthorization:
1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided to support a positive clinical response (i.e. reduction in itch severity and/or hive count).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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**MODERATE TO SEVERE PERSISTENT ASTHMA**

For initial authorization:
1. Member must be 6 years of age or older; AND
2. Medication must be prescribed by on in consultation with a pulmonologist, immunologist or allergist; AND
3. Member has allergy testing performed, as indicated by:
   a) Positive skin testing for perennial aeroallergen; AND/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:** 75 to 375 mg by subcutaneous injection every 2 or 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.
For **reauthorization**:  
1. Medication is not being used as monotherapy for asthma; AND  
2. Member must be in compliance with all other initial criteria; AND  
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:  
   a) Decreased frequency of emergency department visit 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 member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.*

CareSource considers Xolair (omalizumab) not medically necessary for the treatment of the diseases that are not listed in this document.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/18/2017</td>
<td>New policy for Xolair created. For CIU urticaria activity score, trial of oral corticosteroids and trial length added.</td>
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<tr>
<td>01/12/2021</td>
<td><strong>Persistent Asthma</strong>: 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. <strong>CIU</strong>: 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 <strong>Nasal Polyps</strong> added.</td>
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References:


Effective date: 07/01/2021
Revised date: 01/12/2021