CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Xolair (omalizumab)
BILLING CODE	J2357 (1 unit = 5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— see dosage allowed
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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:

10. Member must be 12 years of age or older; AND
11. Medication must be prescribed by or under the recommendation of a dermatologist, allergist, or immunologist; AND
12. Member has a diagnosis of Chronic Idiopathic Urticaria that has been continuously or intermittently present for at least 6 weeks; AND
13. 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).
14. **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**:

4. Member must be in compliance with all other initial criteria; AND
5. 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.

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.

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.

References:

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13. Laidlaw TM, Buchheit KM. Biologics in chronic rhinosinusitis with nasal polyposis. *Ann Allergy Asthma Immunol*. 2020;124(4):326-332. doi:10.1016/j.anai.2019.12.001.

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