CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina 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)

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 idiopathic urticaria and for the add-on maintenance treatment of adults with nasal polyps.

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. 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/Quantity limit:** 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 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, unless not tolerated or contraindicated; 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 Idiopathic Urticaria (CIU)

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 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/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 16 weeks.

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; 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/Quantity limit:** 75 to 375 mg by subcutaneous injection every 2 or 4 weeks.

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 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 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

References:

1. Xolair [package insert]. South San Francisco, CA: GenetechUSA, Inc; December, 2020.
2. Buhl R. Omalizumab (Xolair) improves quality of life in adult patients with allergic asthma: A review. Respir Med. 2003;97(2):123-129.
3. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. J Allergy Clin Immunol. 2003;111(2):278-284.
4. Bang LM, Plosker GL. Omalizumab: A review of its use in the management of allergic asthma. Treat Respir Med. 2004;3(3):183-199.
5. Difficult-To-Treat & Severe Asthma in Adolescent and Adult Patients: Diagnosis and Management. Global Initiative For Asthma (GINA); Apr. 2019. Available at: https://ginasthma.org/wp-content/uploads/2018/11/GINA-SA-FINAL-wms.pdf.
6. 2020 Focused Updates To The Asthma Management Guidelines. National Institute of Health; Dec 2020. Available at: https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates.
7. 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):1270-1277. doi:10.1016/j.jaci.2014.02.036
8. 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): 1355-1566. doi.org/10.1111/all.13397.

9. Gevaert P, Omachi TA, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. *J Allergy Clin Immunol*. 2020;146(3):595-605.
10. Stevens WW, Schleimer RP, Kern RC. Chronic Rhinosinusitis with Nasal Polyps. *J Allergy Clin Immunol Pract*. 2016;4(4):565-572. doi:10.1016/j.jaip.2016.04.012.
11. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. *Ann Allergy Asthma Immunol*. 2014;113(4):347-85. DOI: 10.1016/j.anai.2014.07.025.
12. Sedaghat AR. Chronic rhinosinusitis. *Am Fam Physician*. 2017;96(8):500.506.
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.
14. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement of allergy and rhinology: rhinosinusitis. *Int Forum Allergy Rhinol*. 2016 Feb;6 Suppl 1:S22-209. doi: 10.1002/alr.21695.
15. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. *Allergy*. 2019 Dec;74(12):2312-2319. doi: 10.1111/all.13875.

Effective date: 01/01/2023
Revised date: 02/24/2022