Corporate Medical Policy: Omalizumab (Xolair®)

Restricted Product(s):

- omalizumab (Xolair®) subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- For treatment of moderate to severe persistent asthma in patients 6 years or older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- For treatment of chronic idiopathic urticaria in patients 12 years or older who remain symptomatic despite H1 antihistamine use
- For add-on maintenance treatment of nasal polyps in patients 18 years or older with inadequate response to nasal corticosteroids
- For treatment of IgE-mediated food allergy in patients 1 year and older for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.
- Limitations of use: Not for treatment of emergency allergic conditions, including anaphylaxis or other forms of urticaria, or for acute bronchospasm or status asthmaticus

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

Initial Criteria for Approval:

1. The patient has a diagnosis of **moderate to severe persistent asthma**; **AND**
    a. The patient is 6 years of age or older; **AND**
        i. For patients 6 to 11 years of age, the pre-treatment IgE level is between 30 and 1300 IU/mL **[medical record documentation required]**; **OR**
        ii. For patients 12 years of age or older, the pre-treatment IgE level is between 30 and 700 IU/mL **[medical record documentation required]**; **AND**
    b. The patient has a positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
    c. The patient's symptoms are inadequately controlled despite adherence to use of a medium dose inhaled corticosteroid with combination therapy (long acting inhaled B2 agonist or leukotriene modifier) for at least 3 months; **OR**
    d. The patient requires chronic systemic corticosteroids or high dose inhaled corticosteroids to maintain adequate control of symptoms; **OR**

2. The patient has a diagnosis of **chronic idiopathic urticaria (CIU)**; **AND**
    a. The patient is 12 years of age or older; **AND**
    b. ONE of the following:
        i. The patient has tried and had an inadequate response to ONE maximally tolerated second generation H1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) for at least a 2-week trial **[medical record documentation required**]; **OR**
        ii. The patient has an intolerance or hypersensitivity to second generation H1 antihistamine therapy **[medical record documentation required]**; **OR**
        iii. The patient has an FDA labeled contraindication to ALL second generation H1 antihistamines **[medical record documentation required]**; **AND**
    c. The requested dose is within the FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks; **OR**

3. The patient has a diagnosis of **chronic rhinosinusitis with nasal polyposis**; **AND**
    a. The patient is 18 years of age or older; **AND**
    b. The patient has tried and had an inadequate response to OR has a clinical contraindication or intolerance to Xhance (fluticasone propionate nasal spray) **[medical record documentation required]**; **OR**
    c. The patient has tried and had an inadequate response to OR has a clinical contraindication or intolerance to oral systemic corticosteroids within the previous 6 months **[medical record documentation required]**; **AND**
    d. ONE of the following:
        i. The patient has had prior surgery for nasal polyps **[medical record documentation required]**; **OR**
        ii. The patient is not a candidate for sinus surgery **[medical record documentation required]**; **AND**
    e. The patient will NOT be using Xolair (omalizumab) in combination with Xhance (fluticasone propionate nasal spray); **AND**
    f. ONE of the following:
        i. The patient is currently being treated with an over the counter intranasal steroid; **OR**
        ii. The patient has a clinical contraindication or intolerance to ALL intranasal steroids **[medical record documentation required]**; **AND**

4. The patient has a diagnosis of **IgE-mediated food allergy**; **AND**
    a. The patient is 1 year of age or older; **AND**
    b. The medication will be used in conjunction with food allergen avoidance **[medical record documentation required]**; **AND**

5. The patient is NOT being treated for acute bronchospasm, status asthmaticus, allergic rhinitis, or for treatment of emergency allergic reactions, including anaphylaxis; **AND**

6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, pulmonologist, immunologist, otolaryngologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
7. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication [e.g., benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair)]; **AND**
8. The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
    a. Inability to self-administer the medication; **AND**
    b. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**
9. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
10. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

Continuation Criteria for Approval:

1. The patient has been previously approved for omalizumab (Xolair) through Blue Cross NC initial criteria for approval; **OR**
2. The patient would have met initial criteria for approval at the time they started therapy; **AND**
3. For patients with a diagnosis of **asthma**, they have demonstrated one or more of the following while using the medication **[medical record documentation required]**:
    a. Decreased utilization of rescue medications;
    b. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids);
    c. Increase in predicted FEV1 from pretreatment baseline;
    d. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing; **OR**
4. For patients with **chronic idiopathic urticaria**, they have demonstrated one or more of the following while using the medication **[medical record documentation required]**:
    a. Decreased utilization of rescue and/or chronic controller medications;
    b. Decreased frequency of exacerbations;
    c. Reduction in reported urticaria-related symptoms, such as itching and/or hives; **OR**
5. For patients with **chronic rhinosinusitis with nasal polyposis**:
    a. The patient has been on and adherent to an over the counter intranasal steroid since starting omalizumab (Xolair) therapy; **OR**

   b. The patient has a clinical contraindication or intolerance to ALL intranasal steroids **[medical record documentation required]**; **AND**
6. For patients with **IgE-mediated food allergy**, they have demonstrated the following while using the medication **[medical record documentation required]**:
   a. Reduction in reported dose-limiting symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) to the food allergen; **AND**
   b. The patient will continue to use medication conjunction with food allergen avoidance; **AND**
7. The patient is NOT being treated for acute bronchospasm, status asthmaticus, allergic rhinitis, or for treatment of emergency allergic reactions, including anaphylaxis; **AND**
8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, pulmonologist, immunologist, otolaryngologist) or has consulted with a specialist in the area of the patient's diagnosis; **AND**
9. The patient will NOT receive the requested agent in combination with another biologic immunomodulator agent used for the same indication [e.g., benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair)]; **AND**
10. The patient has a physical or cognitive limitation that makes the utilization of a self-administered formulation unsafe or otherwise not feasible, as demonstrated by BOTH of the following **[medical record documentation required]**:
    a. Inability to self-administer the medication; **AND**
    b. Lack of caregiver or support system for assistance with administration of self-administered products; **AND**
11. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below); **AND**
12. For requests for injection or infusion administration of the requested medication in an **inpatient or outpatient hospital setting,** Site of Care Criteria applies (outlined below)*

Duration of Approval: 365 days (1 year)

FDA Label Reference				
Medication	**Indication*,^**	**Dosing**	**HCPCS**	**Maximum Units***
omalizumab (Xolair®) subcutaneous (SC) injection	Moderate to severe persistent asthma in patients ≥6 years old	SC: 75 mg to 375 mg every 2-4 weeks. Dose and frequency determined by pre-treatment serum total IgE level.	J2357	1950

	Chronic idiopathic urticaria in patients ≥12 years old	SC: 150 mg or 300 mg every 4 weeks		780
	Nasal polyps in patients ≥18 years old	SC: 75 mg to 600 mg every 2-4 weeks. Dosing and frequency determined by pre-treatment serum total IgE level.		3120
	IgE-mediated food allergy in patients ≥1 year old	SC: 75 mg to 600 mg every 2-4 weeks. Dosing and frequency determined by pre-treatment serum total IgE level.		3120

***** Omalizumab is not indicated for treatment of other allergic conditions, other forms of urticaria, relief of acute bronchospasms, or status asthmaticus.
^Omalizumab has not been studied for use in combination with Cinqair (reslizumab) or Nucala (mepolizumab)

***Maximum units allowed for duration of approval**

***Site of Care Medical Necessity Criteria**

1. For requests for injection or infusion administration in an **inpatient setting**, the injection or infusion may be given if the above medical necessity criteria are met AND the inpatient admission is NOT for the sole purpose of administering the injection or infusion; **OR**
2. For requests for injection or infusion administration in an **outpatient hospital setting**, the injection or infusion may be given if the above medical necessity criteria are met AND ONE of the following must be met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.); **OR**
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity; **OR**
    c. New to therapy, defined as initial injection or infusion OR less than 3 months since initial injection or infusion; **OR**
    d. Re-initiation of therapy, defined as ONE of the following:
        i. First injection or infusion after 6 months of no injections or infusions for drugs with an approved dosing interval less than 6 months duration; **OR**
        ii. First injection or infusion after at least a 1-month gap in therapy outside of the approved dosing interval for drugs requiring every 6 months dosing duration; **OR**

e. Requirement of a change in the requested restricted product formulation; **AND**

3. If the Site of Care Medical Necessity Criteria in #1 or #2 above are not met, the injection or infusion will be administered in a **home-based infusion** or physician office setting with or without supervision by a certified healthcare professional.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information: Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q2 annually.

March 2024: Criteria change: Added new indication for Xolair in adult and pediatric patients 1 year and older with IgE-mediated food allergy for reduction of allergic reactions, with corresponding criteria and dosing table updates and added maximum units.
January 2023: Criteria update: Added requirement within initial criteria for asthma indication that patient must be adherent to use of a medium dose inhaled corticosteroid with combination therapy. Minor formatting adjustments made to policy. **Policy notification given 11/1/2022 for effective date 1/1/2023**.
July 2022: Criteria change: Updated step therapy requirement through second generation H1 antihistamine and included maximum dosing for chronic idiopathic urticaria. **Policy notification given 5/2/2022 for effective date 7/1/2022**.
May 2022: Criteria update: Updated chronic rhinosinusitis with nasal polyposis indication to allow trial and failure of Xhance OR oral systemic corticosteroids.
January 2022: Criteria change: Adjusted criteria for chronic rhinosinusitis with nasal polyposis to allow for patients who are not a candidate for sinus surgery.
January 2022: Criteria change: Added requirement for use of the self-administered product unless certain criteria are met. For nasal polyposis indication: added requirement of step through Xhance, removed requirement for nasal saline irrigations, and added requirement for previous surgery for nasal polyps. **Policy notification given 11/4/2021 for effective date 1/4/2022**.
April 2021: Criteria change: Added requirement to be prescribed by or in consultation with a specialist; added maximum units; medical policy formatting change. **Policy notification given 2/26/2021 for effective date 4/28/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.