Generic Name: Omalizumab

Therapeutic Class or Brand Name: Xolair

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/27/2015

Date Last Reviewed / Revised: 9/27/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IV are met)

I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

A. Moderate to severe persistent asthma

1. Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen.
2. Documentation that the patient has been on a minimum of a six-month trial of a high-dose inhaled corticosteroid (ICS) used in combination with a long-acting inhaled beta-2 agonist (LABA)
3. Documentation that the patient's asthma symptoms are poorly controlled despite therapy AND meets at least one of the following criteria 1 through 4:
   a) Poor symptom control (eg, Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
   b) Two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months.
   c) One or more asthma exacerbations requiring emergency treatment (ie, hospitalization, mechanical ventilation, emergency room visit) within the past 12 months.
   d) Worsening asthma when oral corticosteroids are tapered.
   e) Baseline forced expiratory volume in one second (FEV1) < 80% predicted.
4. Requested dosage is in accordance with documented pre-treatment serum IgE levels and the patient's weight as listed in the prescribing information.
5. Minimum age requirement: 6 years old.

B. Chronic idiopathic urticaria

1. Documentation that a medical evaluation has been performed to rule out other possible causes of urticaria.

2. Documented treatment failure or contraindication to ALL of the following drug regimens a to c:
    a) H1-antihistamine therapy taken at the maximally tolerated dose.
    b) H1-antihistamine used in combination with an H2-antihistamine.
    c) H1-antihistamine used in combination with a leukotriene receptor antagonist.
3. Minimum age requirement: 12 years old.

C. Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Documentation that the patient has had 2 of the following signs/symptoms for 12 weeks or longer:
    a) Facial pain, pressure, or fullness
    b) Nasal blockage, obstruction, or congestion
    c) Purulent drainage
    d) Reduced or absent sense of smell
2. Documentation nasal polyps are present by one of the following:
    a) Sinus CT
    b) Nasal endoscopy
    c) Sinus MRI
3. Documentation patient's symptoms are inadequately controlled with a high-dose intranasal corticosteroid used for a minimum of 4 weeks.
4. Xolair will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
5. Patient has received treatment with oral corticosteroids to reduce size of nasal polyps OR had a polypectomy.
6. Requested dosage is in accordance with documented pre-treatment serum IgE levels and the patient's weight as listed in the prescribing information.
7. Minimum age requirement: 18 years old.

D. IgE-mediated food allergy

1. Documentation of baseline immunoglobulin (Ig)E level ≥ 30 IU/mL
2. Documentation of both of the following, a and b.
    a) Positive skin prick test response to one or more foods
    b) Positive in vitro test (ie, blood test) for IgE to one or more foods

3. Documented history of one type 1 allergic reaction that meets ALL of the following a to c:
    a) Signs and symptoms of a significant systemic allergic reaction (ie, hives, swelling, wheezing, hypotension, and gastrointestinal symptoms).
    b) Occurred within a short period of time after known ingestion of the food
    c) Required prescription of an epinephrine auto-injector
4. Documentation that Xolair will be used with a food allergen-avoidant diet
5. Documentation that the member has been prescribed an epinephrine auto-injector.
6. Minimum age requirement: 1 year

II. Treatment must be prescribed by or in consultation with an allergist, dermatologist, immunologist, or pulmonologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Treatment of other allergic conditions or other forms of urticaria.
- Treatment of acute bronchospasm or status asthmaticus.
- Concurrent use with other monoclonal antibodies (ie, Cinqair (reslizumab), Dupixent (dupilumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab)).
- Emergency treatment of allergic reactions, including anaphylaxis.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Asthma: Doses 75 mg to 375 mg every 2 or 4 weeks dependent on IgE and body weight.
- Chronic idiopathic urticaria: Doses 150 mg or 300 mg every 4 weeks.
- CRSwNP: Doses 75 mg to 600 mg every 2 or 4 weeks dependent on IgE and body weight.
- IgE-Mediated food allergy: Doses 75 mg to 600 mg every 2 or 4 weeks dependent on IgE and body weight

Approval Length

- **Authorization:** 6 months.
- **Re-Authorization:** 12 months, with an updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

Appendix

- N/A

References

1. Xolair. Prescribing information. Genentech; 2024. Accessed June 20, 2024. http://www.gene.com/download/pdf/xolair_prescribing.pdf.
2. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC), Cloutier MM, Baptist AP, et al. 2020 Focused updates to the asthma management guidelines: A report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. *J Allergy Clin Immunol*. 2020;146(6):1217-1270. doi:10.1016/j.jaci.2020.10.003
3. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescent and adult patients: diagnosis and management V4.0. August 2023. Accessed October 15, 2023. https://ginasthma.org/severeasthma/
4. 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
5. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol*. 2023;151(2):386-398. doi:10.1016/j.jaci.2022.10.026
6. Wood RA, Togias A, Sicherer SH, et al. Omalizumab for the Treatment of Multiple Food Allergies. *N Engl J Med*. 2024;390(10):889-899. doi:10.1056/NEJMoa2312382