MEDICATION POLICY:

Omalizumab

Generic Name: N/A

Therapeutic Class or Brand Name: N/A

Applicable Drugs (if Therapeutic Class): Omlyclo (omalizumab-igec), Xolair (omalizumab)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/27/2015

Date Last Reviewed / Revised: 5/11/2026

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 allergic asthma

1. Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen.
2. Documented baseline immunoglobulin (Ig)E level of at least 30 IU/mL.
3. 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).
4. Documentation that the patient's asthma symptoms are poorly controlled despite therapy AND meets at least one of the following criteria:
   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, or 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) less than 80% predicted.
5. Documentation that Xolair will be used in conjunction with ICS + LABA therapy as an add-on maintenance treatment.
6. Minimum age requirement: 6 years old.

B. Chronic spontaneous urticaria (CSU)

1. Meets all specified criteria outlined in the Targeted Immune Modulator policy.

C. Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Documentation that the patient has had two or more of the following signs and symptoms for at least 12 weeks:
    a) Facial pain, pressure, or fullness
    b) Nasal blockage, obstruction, or congestion
    c) Purulent drainage
    d) Reduced or absent sense of smell
2. Documented presence of nasal polyps by one of the following:
    a) Sinus CT
    b) Nasal endoscopy
    c) Anterior rhinoscopy
    d) Sinus MRI
3. Documented treatment failure, intolerance, or contraindication to an intranasal corticosteroid used for a minimum of 4 weeks.
4. Documented treatment failure, intolerance, or contraindication to an oral corticosteroid to reduce size of nasal polyps OR had a polypectomy.
5. Documentation that Xolair will be used in conjunction with a nasal corticosteroid as an add-on maintenance treatment.
6. Documented baseline immunoglobulin (Ig)E level of at least 30 IU/mL.
7. Minimum age requirement: 18 years old.

D. IgE-mediated food allergy

1. Documentation of one of the following criteria (a, b, or c):
    a) Positive skin prick test response to one or more foods.
    b) Positive blood test for immunoglobulin (Ig)E to one or more foods.
    c) Positive oral food challenge test.
2. Documented history of allergic reactions that meets all the following criteria:
    a) Signs and symptoms of a significant systemic allergic reaction (eg, hives, swelling, wheezing, hypotension, or gastrointestinal symptoms).
    b) Occurred within a short period of time (eg, 2 hours) after known ingestion of the food.
    c) Required prescription of an epinephrine auto-injector.

3. Documentation that Xolair will be used in combination with a food allergen-avoidant diet.
4. Documented baseline IgE level of at least 30 IU/mL.
5. Minimum age requirement: 1 year

II. Treatment must be prescribed by or in consultation with an allergist, dermatologist, immunologist, otolaryngologist, 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 acute bronchospasm or status asthmaticus.
- Concurrent use with other anti-asthma monoclonal antibodies (ie, Cinqair [reslizumab], Dupixent [dupilumab], Exdensur [depemokimab], Fasenra [benralizumab], Nucala [mepolizumab], and Tezspire [Tezepelumab]).
- Emergency treatment of allergic reactions, including anaphylaxis.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Requested dosage must be in accordance with documented pre-treatment serum IgE levels and body weight (refer to FDA labeling).
- Asthma: Doses 75 mg to 375 mg every 2 or 4 weeks dependent on IgE and body weight.
- 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 May 5, 2026. http://www.gene.com/download/pdf/xolair_prescribing.pdf.
2. Omlyclo. Prescribing information. Celltrion; 2025. Accessed May 11, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761399s000lbl.pdf
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2026. Accessed May 6, 2026. https://ginasthma.org/2026-gina-strategy-report/
4. Payne SC, McKenna M, Buckley J, et al. Clinical Practice Guideline: Adult Sinusitis Update. *Otolaryngol Head Neck Surg*. 2025;173 Suppl 1:S1-S56. doi:10.1002/ohn.1344
5. Santos AF, Riggioni C, Agache I, et al. EAACI guidelines on the diagnosis of IgE-mediated food allergy. *Allergy*. 2023;78:3057-3076. doi:10.1111/all.15902
6. Anagnostou A, Bird JA, Chinthrajah S, et al. The use and implementation of omalizumab as food allergy treatment: Consensus-based guidance and Work Group Report of the Adverse Reactions to Foods Committee of the American Academy of Allergy, Asthma & Immunology. *Journal of Allergy and Clinical Immunology*. 2024;155(1):62-69.e1. doi:10.1016/j.jaci.2024.09.031