SmartHealth Ascension

Omalizumab

(Xolair®) J2357 (5 mg)

Covered with prior authorization

Omalizumab (Xolair®) may be authorized when the following criteria are met:

Moderate to Severe Persistent Asthma

- Individual is ≥ 6 years of age; **AND**
- Individual has a diagnosis of moderate to severe persistent asthma; **AND**
- Individual had an inadequate response to at least medium-dose inhaled corticosteroids (ICS) **and** at least one controller drug **and/or** oral corticosteroids for at least 3 months; **AND**
- Individual has a serum total Immunoglobulin E (IgE) equal to or greater than 30 IU/mL; **AND**
- Individual has a pretreatment forced expiratory volume in one second (FEV1) less than 80% predicted; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
- Dose is 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks based on pretreatment serum total IgE level (IU/mL)t and actual body weight (kg).

Nasal Polyps

- Individual is 18 years of age or older; **AND**
- Individual has a diagnosis of nasal polyps; **AND**
- Documentation is provided that presence of bilateral nasal polyps demonstrated on by one of the following:
    - Anterior rhinoscopy; **OR**
    - Nasal endoscopy; **OR**
    - Computed tomography (CT); **AND**

- Individual has had a trial and inadequate response to maintenance intranasal corticosteroids; **AND**
- Individual is requesting Xolair as add-on therapy to maintenance intranasal corticosteroids; **AND**
- Individual has a serum IgE level greater than or equal to 30 IU/mL; **AND**
- Dosing is appropriate based on FDA guidelines, pretreatment serum IgE and actual body weight (kg).

Chronic Spontaneous Urticaria

- Individual is 12 years of age or older; **AND**
- Individual has a diagnosis of chronic spontaneous urticaria (CSU); **AND**

- Individual has had a trial and inadequate response or intolerance to H1 antihistamines and H2 antihistamines; **AND**
- Dose is 150 to 300 mg every 4 weeks.

IgE-mediated food allergy

- Individual is 1 year of age or older; **AND**
- Individual has a diagnosis of IgE-mediated food allergy; **AND**
- Diagnosis is confirmed via:
    A. Clinical history of IgE-mediated food allergy demonstrated by moderate to severe symptoms (including but not limited to throat tightness, dyspnea/wheezing, clinically significant hypotension, generalized urticaria) or requiring administration of epinephrine or emergency medical care; **AND**
    B. Tests confirming IgE sensitization, such as positive skin prick test or positive serum IgE test or positive food challenge; **AND**
- Individual has a serum IgE level equal to or greater than 30 IU/mL; AND
- Individual will use Xolair in combination with food allergen avoidance; **AND**
- Individual has a prescription for an auto-injectable epinephrine agent; **AND**
- Dose is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on pretreatment serum total IgE level (IU/mL) and actual body weight (kg).

Exclusion criteria:

- Individuals for whom a dose cannot be recommended based on age, weight, and pretreatment IgE.
- Severe hypersensitivity reaction to omalizumab or any component of the formulation;
- Individuals with acute bronchospasm or status asthmaticus.
- Not indicated for the emergency treatment of allergic reactions, including Anaphylaxis.
- Not indicated for other forms of urticaria,
- Will not be used in combination with another antiasthmatic monoclonal antibody (for example, Cinqair, Dupixent, Fasenra, Nucala, or Tezspire).
- Individuals with other allergic conditions or other forms of urticaria different from FDA approved indications above.
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Xolair® is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
- Allergy to food, IgE-mediated allergic reaction (Type 1); Reduction of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy; to be used in conjunction with food allergen avoidance.

References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. Accessed April 15, 2025; ***https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7f6a2191-adfb-48b9-9bfa-0d9920479f0d***
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
3. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. NIH Publication Number 08-5846.
4. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et.al. American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNS). Clinical Practice Guideline (Update): Adult Sinusitis. Otolaryngology-Head and Neck Surgery. 2015;152(2S)SI-S39
5. Xolair® (omalizumab) [prescribing information] Genentech Inc.; 02/2024.

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Medical Specialty Respiratory Drug Review for SmartHealth SBAR developed by Ambulatory Care Expert REview Panel
January 2022	Approved by Ambulatory Care Steering Committee
February 2022	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team

Date	Summary of Changes
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group
Oct 2023	Criteria for use summary revised by Ascension Medical Specialty Prior Authorization Team
December 2023	Criteria for use summary approved by the Ascension Medication Specialty Prior Authorization Expert Review Panel.
February 2024	Updated criteria for use approved by the Ascension Therapeutic Affinity Group.
April 2025	Criteria for use summary revised by Ascension Medical Specialty Prior Authorization Team
April 2025	Revised criteria for use summary approved by the Ascension Medication Specialty Prior Authorization Expert Review Panel.
July 2025	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.