# Omalizumab Products: Xolair

**Policy Statement:**

Xolair (omalizumab) is covered under the Pharmacy Benefit for Medicaid members and covered under the Medical Benefit for Medicaid, Commercial and Medicare members when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**
Coverage of Xolair (omalizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

***Initial Criteria:***
For all indications:

- Must not be used in combination with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenra, Nucala, Xolair (omalizumab), Tezspire, Rhapsido)

**Asthma**

- Member is 6 years of age or older; AND
- Xolair (omalizumab) is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Documentation that member weighs between 20 kg (44 lbs) and 150 kg (330 lbs); AND
- Documentation the member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen; AND
- Member has documentation of pre-treatment IgE level of either:
    - ≥ 30 IU/mL and ≤ 700 IU/mL in members 12 years of age and older; OR
    - ≥ 30 IU/mL and ≤ 1300 IU/mL in members age 6 to < 12 years; AND
- Member has documentation of moderate or severe asthma (see Appendix); AND
- Member is adherent to current treatment with both of the following medications at optimized doses
    - Inhaled corticosteroid; AND
    - Additional controller (long-acting beta$_2$-agonist, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated AND

- Documentation the member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations); AND
- Documentation of baseline measurement of at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    - Forced expiratory volume in 1 second ($FEV_1$), AND
- Member will use Xolair (omalizumab) as add-on maintenance treatment; AND
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (*other than indicated*).

**Chronic spontaneous urticaria**

- Member is 12 years of age or older; AND
- Xolair (omalizumab) is prescribed by, or in consultation with, an allergist/immunologist or dermatologist; AND
- Documentation the member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and is not considered to have any other form(s) of urticaria; AND
- Member is avoiding triggers (e.g., NSAIDs, etc.); AND
- Member's baseline documentation score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL), is provided; AND
- Documentation the member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks; AND
- Documentation the member remains symptomatic despite treatment with up-dosing up to fourfold (in accordance with EAACI/GA2LEN/EuroGuiDerm/APAAACI guidelines) of second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks

  *Note: renewals will require a documented score from an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL, etc.) recorded within the previous 6 months.*

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Member is at least 18 years of age; AND
- Xolair (omalizumab) is being prescribed by or in consultation with an allergist, immunologist or otolaryngologist; AND
- Documentation member has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; AND
- Documentation member has failed at least 8 weeks of daily intranasal corticosteroid therapy; AND
- Documentation the member meets ONE of the following:
    - Member has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
    - Member has a contraindication to systemic corticosteroid therapy; OR
    - Member has had prior surgery for nasal polyps; AND
- Documentation the member does not have any of the following:
    - Antrochoanal polyps
    - Nasal septal deviation that would occlude at least one nostril
    - Disease with lack of signs of type 2 inflammation
    - Cystic fibrosis
    - Mucoceles; AND
- Documentation that other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); AND
- Documentation that physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

**IgE-mediated food allergy:**

- Member is at least 1 year of age**;** AND
- Xolair (omalizumab) is prescribed by, or in consultation with, an allergist/immunologist; AND
- Member is avoiding known food allergens; AND
- Documentation member is allergic to peanut and at least one other food (e.g., milk, egg, wheat, tree nuts, etc.); AND
- Documentation member's allergy has been confirmed by <u>all</u> of the following:
    - Positive skin prick test (SPT), defined as wheal ≥4 mm larger than saline control
    - Positive peanut and food specific IgE, defined as ≥6 IU/mL at screening or within three months of screening

  - Positive double-blind placebo-controlled food challenge (DBPCFC), defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg of peanut protein and ≤300 mg of food protein; AND
- Will not be used for the emergency treatment of allergic reactions, including anaphylaxis

***Continuation of Therapy Criteria:***

**Asthma**

- Member is 6 years of age or older; AND
- Xolair (omalizumab) is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Member weighs between 20 kg (44 lbs) and 150 kg (330 lbs); AND
- Documentation member is tolerating treatment; AND
- Documentation of asthma control has improved/stabilized on Xolair (omalizumab) treatment from baseline as demonstrated by at least one of the following:
  - A reduction in the frequency and/or severity of symptoms and exacerbations; OR
  - A reduction in the daily maintenance oral corticosteroid dose; AND
- Member will use Xolair (omalizumab) as add-on maintenance treatment; AND
- Member will not use Xolair (omalizumab) concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).

**Chronic spontaneous urticaria**

- Member is 12 years of age or older; AND
- Xolair (omalizumab) is prescribed by, or in consultation with, an allergist/immunologist or dermatologist; AND
- Documentation member is tolerating treatment; AND
- Documentation that member has experienced clinical improvement since initiation of Xolair (omalizumab) therapy as documented by improvement from baseline using an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL) within the previous 6 months

**Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)**

- Documentation of improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.).

**IgE-mediated food allergy:**

- Member is at least 1 year of age; AND
- Xolair (omalizumab) is prescribed by, or in consultation with, an allergist/immunologist; AND
- Provider attests that the member has been reassessed and continued therapy is necessary for the maintenance treatment of this condition; AND
- Documentation member has had a reduction in allergic reaction, including anaphylaxis, and/or symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) associated with accidental exposure of known food allergens; AND
- Member will continue to maintain a food-allergen avoidance diet.

**Coverage durations:**

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

**Quantity Limit (Pharmacy Benefit)**

- Xolair (omalizumab) 75mg/0.5 ml syringe - 2 syringes per 28 days
- Xolair (omalizumab) 150mg/ml syringe – 8 syringes per 28 days
- Xolair (omalizumab) 150mg vial – 8 vials per 28 days
- Xolair (omalizumab) 300mg/2ml syringe and autoinjector - 4 syringes/autoinjectors per 28 days

**Dosage/Administration:**

| **Indication** | **Dose** | **Maximum dose (1 billable unit = *5* mg)** |
|---|---|---|
| Allergic Asthma | 75 to 375 mg administered subcutaneously by a health care provider every 2 or 4 weeks | 75 billable units every 14 days |
| Chronic spontaneous urticaria | 150 or 300 mg administered subcutaneously by a health care provider every 4 weeks | 60 billable units every 28 days |
| Nasal polyps | 75 to 600 mg administered subcutaneously by a health care provider every 2 or 4 weeks. . | 120 billable units every 14 days |

| | | |
|---|---|---|
| IgE-mediated food allergy | 75 to 600 mg administered subcutaneously by a health care provider every 2 or 4 weeks. | 60 billable units every 28 days |

| **Criteria for Selection of Members for Self-Administration of Xolair (omalizumab) Prefilled Syringe §§** |
|---|
| • Member should have no prior history of anaphylaxis, including to Xolair (omalizumab) or other agents, such as foods, drugs, biologics, etc.; AND<br>• Member should receive at least 3 doses of Xolair (omalizumab) under the guidance of a healthcare provider with no hypersensitivity reactions; AND<br>• Member or caregiver is able to recognize symptoms of anaphylaxis; AND<br>• Member or caregiver is able to treat anaphylaxis appropriately; AND<br>• Member or caregiver is able to perform subcutaneous injections with Xolair (omalizumab) prefilled syringe with proper technique according to the prescribed dosing regimen and Instructions for Use |
| *Note: Xolair (omalizumab) prefilled syringes for members under 12 years of age should be administered by a caregiver.* |

***Appendix:***

**Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):**

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- Short-acting beta agonist (SABA) use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

**Components of Severity for Classifying Asthma as Moderate may include any of the following (not all inclusive):**

- Daily symptoms
- Nighttime awakenings >1x/week but not nightly
- SABA use for symptom control occurs daily
- Some limitation to normal activities
- Lung function (percent predicted FEV1) >60%, but <80%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

| HCPCS/CPT Code | Description |
|---|---|
| J2357 | Injection, omalizumab, 5 mg |

**References:**

1. Xolair [package insert]. South San Francisco, CA; Genentech, Inc.; December 2025. Accessed January 2026.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA).Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: http://www.ginasthma.org. Accessed April 2018.
4. Baiardini I, Braido F, Bindslev-Jensen C, et al. Recommendations for assessing memberreported outcomes and health-related quality of life in members with urticaria: a GA (2) LEN taskforce position paper. Allergy. 2011 Jul;66(7):840-4. doi: 10.1111/j.1398- 9995.2011.02580.x. Epub 2011 Mar 9.
5. Zuberbier T, Aberer W, Asero R, et al. EAACI/GA (2) LEN/EDF/WAO guideline for the Definition, Classification, Diagnosis and Management of Urticaria. The 2017 Revision and Update.. Allergy. 2018 Jan 15. doi: 10.1111/all.13397.
6. Maurer M, Rosén K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med. 2013 Mar 7;368(10):924-35. doi: 10.1056/NEJMoa1215372. Epub 2013 Feb 24.

7. Siles RI, Hsieh FH. Allergy blood testing: A practical guide for clinicians. Cleve Clin J Med. 2011 Sep;78(9):585-92. doi: 10.3949/ccjm.78a.11023.
8. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014 May;133(5):1270-7.
9. Wisconsin Physician Service Insurance Corp. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicare Services. Updated on 3/20/2018 with effective dates 4/01/2018. Accessed April 2018.
10. First Coast Service Options, Inc. Local Coverage Determination (LCD): Omalizumab (Xolair) (L33924). Centers for Medicare & Medicare Services. Updated on 09/03/2014 with effective dates 10/01/2015. Accessed April 2018.
11. National Government Services, Inc. Local Coverage Article: Omalizumab (e.g., Xolair) – Related to LCD L33394 (A52448). Centers for Medicare & Medicare Services. Updated on 12/24/2015 with effective dates 10/01/2015. Accessed April 2018