Medical Necessity Guidelines
Medical Benefit Drugs
Xolair® (omalizumab)

Effective: July 1, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

The majority of patients can manage their asthma symptoms with a combination of inhaled corticosteroids (ICS) and long-acting beta agonists (LABAs), although a subset of patients remain uncontrolled. Researchers have now developed targeted therapies that yield better outcomes in specific patient types. IgE is central to the development of diseases associated with immediate hypersensitivity reactions, such as allergic asthma. In allergic asthma, IgE production occurs within the bronchial and nasal mucosa, with additional production in the lymphoid tissues and bone marrow. IgE binds to receptors resulting in mast cell release and release of other mediators that contribute to bronchoconstriction and airway inflammation. Xolair is a recommended add-on biologic therapy option for patients with uncontrolled severe asthma despite optimized maximal therapy.

Rhinosinusitis is defined as inflammation of the nose and paranasal sinuses characterized by more than two symptoms including nasal blockage/obstruction and/or nasal discharge (anterior/posterior nasal drip). Biologic therapy targeting T2 inflammation can significantly improve symptoms due to chronic rhinosinusitis with nasal polyps. In patients with chronic rhinosinusitis with nasal polyps, Xolair can improve subjective and objective assessments including nasal symptoms and polyp size, compared to placebo.

Urticaria is a condition characterized by the development of wheals (hives), angioedema, or both. A step wise approach to management includes initial therapy with a second-generation H1-antihistamine. Followed by a dose increase of the second-generation H1-antihistamine or the adjunctive use of an H2-antihistamine or an antileukotriene medication. Third-line treatments includes Xolair and cyclosporine. ASTERIA I (24 weeks) and ASTERIA II (12 weeks) trials support the approval of Xolair for treating moderate-to-severe H1 antihistamine–refractory chronic spontaneous urticaria (CSU). The primary endpoint of the ASTERIA trials was the change from baseline in weekly itch severity score (ISS) (range 0-21) at Week 12, and the Xolair 150 mg and 300 mg doses met the primary endpoint. GLACIAL also supports the FDA approval of Xolair in CSU. GLACIAL evaluated the safety and efficacy of omalizumab 300 mg versus placebo in patients with CSU who remained symptomatic despite receiving up to four times the approved dosage of H1 antihistamines and either an H2 antihistamine or antileukotriene medication, or all three in combination.

Food allergies are broadly categorized into either IgE mediated or non-IgE mediated processes. Patients with Ig-E mediated food allergies typically react to one or two specific foods. IgE-mediated reactions range from mild to moderate, and manifest as urticaria and angioedema, oropharyngeal symptoms, respiratory tract symptoms, gastrointestinal symptoms, or anaphylaxis. Diagnosis of IgE-mediated food allergy includes a combination of clinical history and physical examination, prick skin testing, skin testing, and food challenges. There is no cure for food allergy. Management of food allergy requires strict allergen exposure avoidance, in addition to prompt administration of epinephrine to treat anaphylaxis if accidental exposures occur. Safety and efficacy of Xolair in reducing allergic reactions in patients with food allergies were evaluated in a National Institute of Allergy and Infectious Diseases, placebo-controlled trial which showed a significantly higher proportion of food allergy patients treated with Xolair could tolerate small amounts of peanut, milk, egg and cashew without an allergic reaction, compared to placebo.

Food and Drug Administration (FDA) Approved Indications:

Xolair (omalizumab) 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** as add-on maintenance treatment in adult patients 18 years of age and older with inadequate response to nasal corticosteroids
- **Chronic spontaneous urticaria (CSU)** in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment
- **IgE-Mediated Food Allergy**
  The reduction of allergic reaction (Type I), including anaphylaxis, that may occur with accidental exposure to one ore more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. Xolair is to be used in conjunction with food allergen avoidance. Limitations of Use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xolair when the following criteria is met:

Asthma

1. Documented diagnosis of moderate to severe persistent asthma

AND

2. Documentation of a pre-treatment serum IgE level of at least 30 IU/mL

AND

3. Patient is at least 6 years of age or older

AND

4. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

5. Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen

AND

6. Documentation of **one (1)** of the following:
   a. Previous failure of a treatment regimen that included two or more of the following medications: Inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators
   b. Clinical inappropriateness of inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators

Chronic Spontaneous Urticaria

1. Documented diagnosis of chronic spontaneous urticaria

AND

2. Patient is at least 12 year of age or older

AND

3. Prescribed by or in consultation with an allergist, dermatologist, or immunologist

AND

4. Documentation of **one (1)** of the following:
   a. Previous failure of a treatment regimen that included an H1 antihistamine treatment
   b. Clinical inappropriateness to H1 antihistamine treatment

Chronic Rhinosinusitis with Nasal Polyps

1. Documented diagnosis of nasal polyps

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist

AND

4. Documentation of **one (1)** of the following:
   a. Previous failure of a treatment regimen that included an intranasal corticosteroid
   b. Clinical inappropriateness to intranasal corticosteroids

Ig-E Mediated Food Allergy

1. Documented diagnosis of IgE-mediated food allergy

AND

2. Patient is at least 1 year of age or older

AND

3. Prescribed by or in consultation with allergist or immunologist

AND

4. Documentation of use in conjunction with food allergen avoidance

AND

5. Documentation of a pre-treatment serum IgE level of at least 30 IU/mL

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2357	Injection, omalizumab, 5 mg

References:

1. Bardelas J, Figliomeni M, Kianifard F, Meng X. A 26-week, randomized, double-blind, placebo- controlled, multicenter study to evaluate the effect of omalizumab on asthma control in patients with persistent allergic asthma. J Asthma. 2012 Mar; 49(2):144-52.
2. Buhl R, Solèr M, Matz J, et al. Omalizumab provides long-term control in patients with moderate- to severe allergic asthma. Eur Respir J. 2002; 20:73-78.
3. Buhl R, Hanf G, Solèr M, et al. The anti-IgE antibody omalizumab improves asthma-related quality of life in patients with allergic asthma. Eur Respir J. 2002; 20:1088-1094.
4. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clin Immunol. 2001; 108(2):184- 190.
5. Casale TB, Condemi J, LaForce C, et al. Effect of omalizumab on symptoms of seasonal allergic rhinitis: a randomized controlled trial. JAMA. Dec 19 2001; 286(23):2956-2967.
6. Chipps BE, Figliomeni M, Spector S. Omalizumab: An update on efficacy and safety in moderate -to-severe allergic asthma. Allergy Asthma Proc. 2012 Sep; 33(5):377-85.
7. Domingo C, Pomares X, Angril N, et al. Effectiveness of omalizumab in non -allergic severe asthma. J Biol Regul Homeost Agents. 2013 Jan-Mar; 27(1):45-53.
8. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. J Allergy Clin Immunol. 2003; 111(2):278-284.
9. Holgate S, Bousquet J, Wenzel S, Fox H, Liu J, Castellsague J. Efficacy of omalizumab, an ant immunoglobulin E antibody, in patients with allergic asthma at high risk of serious asthma - related morbidity and mortality. Curr Med Res Opin. 2001; 17(4):233-240.
10. Kaplan A, Ledford D, Ashby M, et al. Omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticaria despite standard combination therapy. 2013 Jul; 132(1):101-9.
11. Kelmenson DA, Kelly VJ, Winkler T, et al. The effect of omalizumab on ventilation and perfusion in adults with allergic asthma. Am J Nucl Med Mol Imaging. 2013 Jul 10; 3(4):350-60.
12. 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.
13. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study. J Invest Dermatol. 2015 Jan;135(1):67-75.
14. Solèr M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. Eur Respir J. 2001; 18:254-261.
15. Sussman G, Hébert J, Barron C, et al. Real-life experiences with omalizumab for the treatment of chronic urticaria. Ann Allergy Asthma Immunol. 2014 Feb; 112(2):170-4.
16. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
17. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, HPHC Pharmacy PA Policy: Page 16 of 17 and Blood Institute, 2007. www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm
18. National Institutes of Health. National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. Available at https://www.ncbi.nlm.nih.gov/books/NBK7232/pdf/Bookshel_NBK7232.pdf. Accessed March 12, 2021.
19. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2020 update. Available at https://ginasthma.org/reports/. Accessed March 08, 2021.
20. Wang J et al. Guidance on completing a written allergy and anaphylaxis emergency plan. Pediatrics. 2017 March;139(3):

e20164005.
21. MacGinnitie AJ, et al. The role of food challenges in clinical practice. J Allergy Clin Immunol Pract. 2018 Mar-Apr;6(2):353-360.
22. Wang J, et al. Guidance on completing a written Allergy and Anaphylaxis Emergency Plan. *Pediatrics* (2017) 139 (3): e20164005.

Approval And Revision History

February 15, 2022: Reviewed by the Medical Policy Approval Committee (MPAC).

March 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T).

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022, by P&T and September 21, 2022, by MPAC committees.
- March 2023 added "Xolair 75mg and 150mg single-dose prefilled syringes are covered under the Member's Prescription Drug Benefit if Xolair is being self-administered" as a limitation effective April 1, 2023.
- November 2023: Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- May 12, 2024: Added coverage criteria for the supplemental indication of Ig-E mediated food allergy. Added provider specialty requirements. Minor wording updates. Removed the Limitations: The Plan may authorize coverage of Xolair (omalizumab) for up to 12 months if coverage criteria are met, Xolair 75mg and 150mg single-dose prefilled syringes are covered under the Member's Prescription Drug Benefit if Xolair is being self-administered, and The Plan does not authorize coverage of Xolair for any indications which are not FDA-approved. For asthma, added Documentation of a pre-treatment serum IgE level of at least 30 IU/mL and Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen (eff 8/1/2024).
- June 10, 2025: No changes (eff 7/1/25)
- June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.