CarePartners of Connecticut

Medical Necessity Guidelines: Xolair® (omalizumab)

Effective: April 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

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 and Drug Administration (FDA) Approved Indications:

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
- Nasal polyps 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

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Xolair (omalizumab) when the following criteria is met:

1. The Member has a documented diagnosis of **one** (a, b or c) of the following:
    a. Moderate to severe persistent asthma, *and*
        i. The Member is 6 years of age or older, *and*
        ii. Has a positive skin test or in vitro reactivity to a perennial aeroallergen, *and*
        iii. The Member has asthma symptoms that are inadequately controlled with inhaled corticosteroids

    OR

    b. Chronic spontaneous urticaria (CSU), *and*
        i. The Member is 12 years of age or older, *and*
        ii. Remains symptomatic despite H1 antihistamine treatment

    OR

    c. Nasal polyps, and
        i. The Member is 18 years of age or older, *and*
        ii. The Member has had an inadequate response to treatment with nasal corticosteroids

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.
- The Plan does not authorize coverage of Xolair for any indications which are not FDA-approved.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2357	Injection, omalizumab, 5 mg

References:

1. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; June 2022. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/103976s5225lbl.pdf
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org.
3. Ghung KF, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. European Respiratory Journal. 2014;43:343-373.
4. Gevaert P, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. J Allergy Clin Immunol 2020;146:595-605.
5. Agache I, et al. Efficacy and safety of treatment with biologicals (benralizumab, dupilumab and omalizumab) for severe allergic asthma: a systematic review for the EAACI Guidelines - recommendations on the use of biologicals in severe asthma. Allergy. 2020;65:1043-57.
6. Saini SS, 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.
7. Maurer M, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med. 2013;368:924-35.
8. Zuberbier T, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022;77(3):734-66.

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.

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.

.