Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Xolair® (omalizumab)

Effective: January 1, 2027

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

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 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

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of moderate to severe persistent asthma allergic asthma with **both** of the following:
   a. Positive skin test or in vitro reactivity to at least one perennial allergen
   b. Pre-treatment serum immunoglobulin E level greater than or equal to 30 international units per milliliter

AND

2. Patient is six (6) years of age or older

AND

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

AND

4. Documentation of **one (1)** of the following within the previous 12 months:
   a. History of two (2) or more asthma exacerbations requiring systemic corticosteroids
   b. Prior asthma-related hospitalization

AND

5. Documentation of history of failure to a minimum three (3) month trial with a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist), unless contraindicated

AND

6. Documentation the requested medication will be used as add-on maintenance therapy with a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist), unless contraindicated

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
   b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
   c. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of moderate to severe persistent allergic asthma

AND

2. Patient is six (6) years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. Increase in percent predicted Forced Expiratory Volume (FEV1) from pretreatment baseline
    b. Reduction in the dose of inhaled corticosteroids required to control asthma
    c. Reduction in the frequency of asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits)
    d. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)
    e. Reduction in the use of oral corticosteroid to treat and/or prevent asthma exacerbations

AND

5. Documentation the requested medication will be used as add-on maintenance therapy with a maximally tolerated inhaled corticosteroid plus at least one other asthma medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist), unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

Chronic Spontaneous Urticaria (CSU)

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic spontaneous urticaria

AND

2. Documentation of persistent symptoms of chronic spontaneous urticaria for at least six (6) weeks despite use of a second generation H1 antihistamine

AND

3. Patient is 12 years of age or older

AND

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

AND

5. Documentation of history of failure to a minimum two (2) week trial with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine), unless contraindicated

AND

6. Documentation the requested medication will be used concurrently with a second-generation H1 antihistamine, unless contraindicated

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria

AND

2. Patient is 12 years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:

a. Reduced itching
b. Reduction in the number and/or size of hives

AND

5. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

Chronic Rhinosinusitis with Nasal Polyps

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Documentation of history of failure to a minimum eight (8) week trial of intranasal corticosteroids, unless contraindicated

AND

5. Documentation the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Documentation the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

AND

5. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbations

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
    b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    c. Anti-interleukin 4 therapy (e.g. dupilumab)

IgE-Mediated Food Allergy

Initial Authorization Criteria

1. Submission of medical charts documenting **one (1)** of the following:
    a. Diagnosis of IgE mediated food allergy as evidenced by clinical history of IgE mediated food allergy and **one (1)** of the following:
        i. Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food

ii. Positive food specific IgE (greater than or equal to 6 kUA/L)
iii. Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein

b. Patient history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

2. Patient is one (1) year of age or older

AND

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

AND

4. Documentation the requested medication will be used in conjunction with food allergen avoidance

AND

5. Documentation of **both** of the following:
   a. Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 international units per microliter
   b. Dosing is according to serum total IgE levels and body weight

AND

6. Documentation the requested medication will not be used for the emergency treatment of allergic reactions, including anaphylaxis

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
   b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
   c. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of Ig-E mediated food allergy

AND

2. Prescribed by or in consultation with an allergist or immunologist

AND

3. Patient is one (1) year of age or older

AND

4. Documentation the requested medication will be used in conjunction with food allergen avoidance

AND

5. Documentation the dose will continue to be based on body weight and pre-treatment total IgE serum levels

AND

6. Documentation the requested agent will not be used for the emergency treatment of allergic reactions, including anaphylaxis

AND

7. Documentation the patient has experienced a clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab, benralizumab)
   b. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
   c. Anti-interleukin 4 therapy (e.g. dupilumab)

Limitations

- Initial approval of Xolair will be authorized for six (6) months. Reauthorization of Xolair will be provided in 12-month intervals

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2357	Injection, omalizumab, 5 mg

References:

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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.
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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.
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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.
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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
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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.
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- 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. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template. (eff 7/1/25)
- June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25).
- September 2026: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26). For Asthma added submission of medical charts confirming diagnosis (Initial), added severity requirements (history of exacerbations or hospitalization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), added confirmation treatment will be used as add-on therapy (Reauthorization), and added aubmission of medical charts confirming objective reauthorization criteria (Reauthorization). For CSU added submission of medical charts confirming diagnosis (Initial), added antihistamine step (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), added confirmation treatment will be used as add-on therapy (Initial), added concurrent therapy language (Initial and Reauthorization), and added submission of medical charts confirming objective reauthorization criteria (Reauthorization). For IgE-medicated Food Allergy added submission of medical charts confirming diagnosis with existing clinical criteria (Initial); added confirmation of non-emergency use (Initial and Reauthorization); added concurrent therapy language (Initial and Reauthorization); added medication will not be used for the emergency treatment of allergic reactions, including anaphylaxis (Initial and Reauthorization); added submission of medical charts confirming broad reauthorization criteria (Reauthorization); and updated initial approval duration from 5 to 6 months. For Chronic Rhinosinusitis with Nasal Polyps added additional objective responses to therapy in objective reauthorization criteria (Reauthorization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), and submission of medical charts confirming objective reauthorization criteria (Reauthorization). Added limited duration of approval (6 and 12 months to limitations section.

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.