Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Xolair® (omalizumab)

Effective: September 1, 2026

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

Public Plans Products

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

☐ Tufts Health Together – MassHealth 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

Food and Drug Administration (FDA) Approved Indications

Xolair (omalizumab) is an anti-IgE antibody indicated for:

- **Asthma**
  Adults and pediatric patients six (6) years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is not indicated for relief of acute bronchospasm or status asthmaticus.
- **Chronic Spontaneous Urticaria**
  The treatment of adults and adolescents 12 years of age and older with chronic spontaneous urticaria 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 or 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. Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- **Chronic Rhinosinusitis with Nasal polyps**
  Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xolair (omalizumab) for Members when **ALL** of 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)

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)

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)

Limitations

- Initial approval of Xolair will be authorized for six (6) months. Reauthorization of Xolair will be provided in 12-month intervals.
- Members new to the plan stable on Xolair should be reviewed against Reauthorization Criteria. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization Criteria.
- Xolair 75mg and 150mg prefilled syringes are covered under the Member's Prescription Drug Benefit if Xolair is being self-administered.

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.

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.
- May 14, 2024: Added coverage criteria for the supplemental indication for IgE-Mediated Food Allergy. For Chronic Idiopathic Urticaria, updated prerequisite trials to be less strict. For Asthma, updated diagnosis requirements to include current treatment with another biologic for moderate to severe asthma. Updated prerequisite trials to be less strict. For Nasal Polyps, removed "Documentation the Member has poor control of nasal symptoms requiring additional treatment despite a 12-week trial of an intranasal corticosteroids. "Removed "Documentation of one of the following: Prior treatment of nasal polyps with systemic corticosteroids within the past two (2) years, contraindication to the use of systemic corticosteroids, or prior nasal polyp removal." Expanded provider specialty requirements. Added the patient will not be concurrently treated with an alternative biologic for nasal polyps. For Reauthorization criteria, added reduction in exacerbations to how a patient can demonstrate a therapeutic response. Minor wording changes (eff 8/1/24).
- May 13, 2025: No changes. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 5/13/25).
- June 9, 2026: Removed Tufts Health RITogether from the Medical Necessity Guideline. Administrative update to remove CareLink from the Medical Necessity Guideline template. For Asthma added submission of medical charts confirming diagnosis (Initial), removed current treatment with an alternative respiratory biologic as confirmation of 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 limitation statement that members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria. (eff 9/1/26). Administrative update: Template updated from “Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans” to “Tufts Health Together- MassHealth Accountable Care Partnership Plans.”
- August 11, 2026: Removed submission of medical records requirements for response to therapy in Reauthorization Criteria (eff 9/1/26).

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is 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.