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:

- **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 (omalizumab) for Members when the following criteria is met:

Allergic Asthma

Initial Authorization Criteria

1. Documentation of **one (1)** of the following:
   a. Documented diagnosis of moderate to severe persistent asthma

b. Current treatment with an alternative biologic indicated for moderate to severe asthma

AND

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

AND

3. Documentation of a positive skin test or in vitro reactivity to at least one perennial allergen

AND

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

AND

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

AND

6. Documentation the patient is currently maintained on 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)

AND

7. The patient will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of moderate to severe persistent asthma

AND

2. Patient is at least 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. The patient will not be concurrently treated with an alternative biologic for asthma

Chronic Idiopathic Urticaria (CIU)

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe chronic idiopathic urticaria defined by presence of the condition for at least six (6) weeks

AND

2. Patient is at least 12 years 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. Patient remains symptomatic despite treatment with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine)
   b. Contraindication to second-generation H1 antihistamines

Reauthorization Criteria

1. Documented diagnosis of moderate to severe chronic idiopathic urticaria

AND

2. Patient is at least 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

IgE-Mediated Food Allergy

Initial Authorization Criteria

1. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. Documented diagnosis of IgE mediated food allergy as evidence by one of the following:
            1. Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food
            2. Positive food specific IgE (greater than or equal to 6 kUA/L)
            3. 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
        ii. Clinical history of IgE mediated food allergy
    b. Provider attestation that the patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

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

AND

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

AND

4. Documentation of use 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 IU/mL
    b. Dosing is according to serum total IgE levels and body weight

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 at least 1 year of age or older

AND

4. Documentation of use 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 patient has experienced a therapeutic response to therapy

Nasal Polyps

Initial Authorization Criteria

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. Patient is concurrently treated with an intranasal corticosteroid
    b. Contraindication to intranasal corticosteroids

AND

5. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Reauthorization Criteria

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. Patient is concurrently treated with intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

AND

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

AND

6. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Limitations

- Initial approval of Xolair will be authorized for six (6) months. Reauthorization of Xolair will be provided in 12-month intervals.
- Patients new to the plan stable on Xolair should be reviewed against Reauthorization 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

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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.
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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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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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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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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 Commercial Products and Tufts Health Direct from Medical Necessity Guideline. Updated duration of approval rules to be Initial 6 months and 12 month Reauthorizations for all indications (eff 9/1/26). Administrative update to template to remove CareLink from the Medical Necessity Guideline template. Administrative update: updated template to read: “Tufts Health Together- MassHealth Accountable Care Partnership Plans; Fax 617-673-0939”, to reflect change.

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.