Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Xolair® (omalizumab)

Effective: April 1, 2023

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

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 Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☐ 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**
- **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) for Members when the following criteria is met:

Moderate to Severe Persistent Asthma

Initial Authorization Criteria

1. The Member has a documented diagnosis of moderate to severe persistent asthma

AND

2. The Member has documentation of a pre-treatment serum IgE level of at least 30 IU/mL

AND

3. The Member shows a definitive sensitivity on allergy testing to **one (1)** or more perennial allergens

AND

4. The Member is at least six (6) years of age or older

AND

5. Xolair is being prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, or pulmonologist)

AND

6. The Member has documentation of poor asthma control* or recurrent exacerbations* requiring additional treatment* despite a 12-week trial of a medium to high-dose inhaled corticosteroid (e.g. fluticasone furoate [Arnuity Ellipta], mometasone furoate [Asmanex], fluticasone propionate [Flovent HFA]) used in combination with **one (1)** of the following:
    a. A long-acting inhaled beta-2 antagonist (LABA) (e.g., formoterol [Perforomist], salmeterol [Serevent]
    b. A leukotriene modifier (e.g., montelukast)
    c. A sustained-release theophylline
    d. The Member is intolerant or has a contraindication to combination therapy to ALL of these medications

AND

7. Documentation that the member will not be treated with Xolair (omalizumab) in combination with another biologic medication for the treatment of asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)

***NOTE:**

- Poor asthma control may include but is not limited to clinical documentation of limitation in activities of daily living, nighttime awakening, or dyspnea
- Recurrent exacerbation is defined as 2 or more acute exacerbations in a 12-month period
- Additional medical treatment may include any of the following: treatment with oral corticosteroids, emergency department visits, hospitalizations, or frequent office visits

Reauthorization Criteria

1. The Member has a documented diagnosis of moderate to severe persistent asthma

AND

2. The Member is at least six (6) years of age or older

AND

3. Xolair is being prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, or pulmonologist)

AND

4. Documentation that the Member 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

    OR

    b. Reduction in the dose of inhaled corticosteroids required to control asthma

    OR

    c. Reduction in the frequency of asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits)

    OR

    d. Reduction in the severity of asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)

    OR

    e. Reduction in the use of oral corticosteroid to treat and/or prevent asthma exacerbations

AND

5. Documentation that the Member will not be treated with Xolair (omalizumab) in combination with another biologic medication for the treatment of asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)

Chronic Idiopathic Urticaria (CIU)

Initial Authorization Criteria

1. The Member has a documented diagnosis of chronic idiopathic urticaria defined by presence of the condition for at least 6 weeks

AND

2. The Member is at least twelve (12) years of age or older

AND

3. Xolair is being prescribed by or in consultation with an allergist, dermatologist or immunologist

AND

4. Documentation that the Member is symptomatic despite:
    a. A two-week trial of a H1 plus H2-antihistamine or a H1-antihistamine plus a leukotriene receptor antagonist

OR

    b. The Member is intolerant or has a contraindication to all of these medications

Reauthorization Criteria

1. The Member has a documented diagnosis of chronic idiopathic urticaria

AND

2. Member is at least twelve (12) years of age or older

AND

3. Xolair is being prescribed by or in consultation with an allergist, dermatologist or immunologist

AND

4. Documentation that the Member has experienced a therapeutic response as defined by at least **one (1)** of the following since initiating treatment with Xolair (omalizumab):
    a. Reduced itching

OR

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

Nasal Polyps

Initial Authorization Criteria

1. The Member has a documented diagnosis of nasal polyps

AND

2. The Member is at least eighteen (18) years of age or older

AND

3. Xolair is being prescribed by an allergist, immunologist, or otolaryngologist

AND

4. Documentation that the Member has poor control of nasal symptoms requiring additional treatment despite a 12-week trial of an intranasal corticosteroid (e.g., Flonase, Nasacort, or Rhinocort)

AND

5. Documentation of **one (1)** of the following:
    a. The Member is concurrently being treated with an intranasal corticosteroid

OR

    b. The Member has a contraindication or intolerance to the use of intranasal corticosteroids

AND

6. Documentation of **one (1)** of the following:
    a. Prior treatment of nasal polyps with systemic corticosteroids within the past two (2) years

OR

    b. Contraindication to the use of systemic corticosteroids

OR

    c. Prior nasal polyp removal

Reauthorization Criteria

1. The Member has a documented diagnosis of nasal polyps

AND

2. The Member is at least eighteen (18) years of age or older

AND

3. Xolair is being prescribed by an allergist, immunologist, or otolaryngologist

AND

4. Documentation of **one (1)** of the following:
    a. The Member is concurrently treated with intranasal corticosteroids

OR

    b. The Member has a contraindication or intolerance to intranasal corticosteroids

AND

5. Documentation the Member 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

Limitations

- The Plan does not cover Xolair (omalizumab) for the following conditions:
  - Treatment of other allergic conditions or other forms of urticaria not listed in the Medical Necessity Guidelines above.
  - Treatment to relieve acute bronchospasm or status asthmaticus.
  - Use in pediatric patients less than 6 years of age (moderate to severe persistent asthma), less than 12 years of age (chronic idiopathic urticaria), or less than 18 years of age (nasal polyps).
- For the treatment of allergic asthma, coverage will not be authorized if the Member is also receiving another biologic medication for the treatment of asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)
- Initial approval will be limited to 6 months.
- Reauthorization approval will be limited to 12 months
- Members new to the plan stable on Xolair (omalizumab) should be reviewed against Reauthorization Criteria for all indications.
- 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. Al Efraij K, FitzGerald JM. Current and emerging treatments for severe asthma. J Thorac Dis. 2015 Nov;7(11):E522-5.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.
13. 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.
14. 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.

15. 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.
16. 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.
17. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; July 2021.

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
- Administrative update: March 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- 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

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.