Pharmacy Medical Necessity Guidelines: Xolair® (omalizumab)

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	MED	Department to Review	MM / PRECERT

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
All plans except Tufts Health Direct – Health Connector:
PRECERT: 617.972.9409

Tufts Health Direct – Health Connector only:
MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMNISTRATION-APPROVED INDICATIONS

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

- **Allergic Asthma**
  Patients 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 (omalizumab) has been shown to decrease the incidence of asthma exacerbations in these patients. Xolair (omalizumab) is not indicated for the relief of acute bronchospasm or status asthmaticus and is not indicated for treatment of other allergic conditions.
- **Chronic Idiopathic Urticaria**
  Adults and adolescents 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment. Xolair (omalizumab) is not indicated for the treatment of other forms of urticaria.

COVERAGE GUIDELINES

The plan may authorize coverage of Xolair (omalizumab) for Members when all of the following criteria are met:

Allergic Asthma

1. Documented diagnosis of moderate to severe allergy-related asthma

AND

2. Documentation of baseline serum IgE level between 30 to 700 IU/mL

AND

3. Documentation of evidence of specific allergic sensitivity (i.e., positive skin test or blood test [radioallergosorbent test or RAST] for IgE)

AND

4. Member is at least 6 years of age

AND

5. Prescribed by an asthma specialist (e.g., allergist, immunologist, or pulmonologist)

AND

6. Documentation the Member is symptomatic despite receiving **one (1)** of the following:
   a. Combination inhaler
   b. Combination of an inhaled corticosteroid and a long-acting beta agonist inhaler
   c. Chronic oral corticosteroids (defined as ≥90 days of therapy within the last 120 days)

Chronic Idiopathic Urticaria (CIU)

1. Documented diagnosis of chronic idiopathic urticaria

AND

2. Member is at least 12 years of age

AND

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

AND

4. Documented inadequate response (defined as ≥14 days of therapy), adverse reaction, or contraindication to at least **two (2)** different histamine$_1$ antihistamines

AND

5. Documented inadequate response (defined as ≥14 days of therapy), adverse reaction, or contraindication to a histamine$_1$ antihistamine in combination with a leukotriene antagonist

AND

6. Documented inadequate response (defined ≥14 days of therapy), adverse reaction, or contraindication to a histamine$_1$ antihistamine in combination with a histamine$_2$ antihistamine

LIMITATIONS

- None

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J2357	Injection, omalizumab, 5 mg

REFERENCES

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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.
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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.
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11. Kaplan A, Ledford D, Ashby M, et al. Omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticaria despite standard combination therapy. *J Allergy Clin Immunol.* 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.; May 2019.

APPROVAL HISTORY

November 24, 2020: Reviewed by Pharmacy & Therapeutics Committee for an effective date of January 1, 2021 for implementation of MassHealth ACPP/MCO Partial Unified Formulary.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be 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 the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy 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 Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.