Pharmacy Medical Necessity Guidelines: Xolair® (omalizumab)

Effective: October 21, 2019

Prior Authorization Required

<table>
<thead>
<tr>
<th>Type of Review – Care Management</th>
<th>Type of Review – Clinical Review</th>
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Not Covered

Pharmacy (RX) or Medical (MED) Benefit

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<tr>
<th>Benefit</th>
<th>Department to Review</th>
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<tr>
<td>MED</td>
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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
- CareLinkSM – 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:

MM: 888.415.9055

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

OVERVIEW

**FOOD AND DRUG ADMINISTRATION-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 (CIU)**
  
  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. The Member is ≥6 years of age

2. The prescribing physician is specializing in allergy or pulmonary medicine

3. The Member has evidence of specific allergy sensitivity, either a positive skin test or in-vitro reactivity to perennial allergen

4. The provider indicated suppressed IgE levels secondary to chronic, systemic steroid use OR documentation of a pre-treatment serum IgE level of:
   
   - Members ≥12 years: ≥30 IU/mL and ≤700 IU/mL
   - Members 6-11 years: ≥30 IU/mL and ≤1,300 IU/mL

5. The Member has at least one of the following criteria to meet the diagnosis of moderate to severe asthma:
   
   - Daily asthma symptoms
   - Frequent exacerbations
   - Nighttime symptoms >1 time a week
   - FEV1 <80%

AND
6. The Member has demonstrated inadequate control of asthma symptoms, despite the use of a treatment regimen which would include an inhaled corticosteroid agent, as indicated by at least one of the following:
   a) Exacerbations leading to ER visits, hospitalizations
   b) Frequent use of short-acting B-agonists
   c) Use of oral corticosteroids
   **AND**
7. Upon renewal, the Member has current evidence of specific allergy sensitivity, either a positive skin test or in-vitro reactivity to perennial allergen and improvement in at least one of the following areas:
   a) 25% reduction in asthma exacerbations
   b) 50% reduction in oral corticosteroid
   c) 25% reduction in inhaled corticosteroid dose

**Chronic Idiopathic Urticaria (CIU)**
1. The Member is ≥12 years of age
   **AND**
2. The Member has a definitive diagnosis of chronic idiopathic urticaria for at least 6 weeks
   **AND**
3. The requesting physician is an allergist, dermatologist or immunologist
   **AND**
4. The requesting physician has documented that the Member remains symptomatic in spite of at least 2 weeks of treatment with a trial of one of the following regimens or documented history of contraindication or intolerance to:
   - H1 plus H2-antihistamine
   - H1-antihistamine plus a leukotriene receptor antagonist
   **AND**
5. The Member is being treated concurrently with an H1-antihistamine
   **AND**
6. Require documentation of medical evaluation for other causes of the urticaria.

**LIMITATIONS**
Initial approval will be limited to 12 months. A new prior authorization may be submitted at that time for continuation of therapy. Subsequent authorization requests may be given in 12-month intervals based on the submission of medical records documenting tolerance and effectiveness of therapy.

**CODES**
The following HCPCS/CPT code(s) are:

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J2357</td>
<td>Injection, omalizumab, 5 mg</td>
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**REFERENCES**

**APPROVAL HISTORY**

June 4, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 9, 2015: Removed disease severity score submission requirement for diagnosis of CIU.
2. January 1, 2016: Administrative change to rebranded template.
3. February 9, 2016: No changes
4. July 12, 2016: Effective October 1, 2016: Changed time frame requirement for diagnosis of chronic idiopathic urticaria from at least 6 months to at least 6 weeks. Changed prerequisite therapy trial time frame from 6 month to at least 2 weeks each. Added history of contraindication or intolerance to prerequisite therapy requirement. Expanded age range for members with moderate to severe persistent asthma to include children 6-11 years of age.
5. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
6. July 11, 2017: No changes
7. September 12, 2017: For the treatment of allergic asthma, updated the pre-treatment serum IgE level requirements in Members 6 to 11 years of age to be ≥30 IU/mL and ≤1,3000 IU/mL. Members ≥12 years of age will continue to require pre-treatment levels of ≥30 IU/mL and ≤700 IU/mL
8. August 7, 2018: No changes
9. September 10, 2019: No changes
10. October 15, 2019: For chronic idiopathic urticaria, updated coverage criteria to require trial of at least one of the following regimens: H1 plus H2-antihistamine or H1-antihistamine plus a leukotriene receptor antagonist.

**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.