Pharmacy Medical Necessity Guidelines: Xolair® (omalizumab)

Effective: August 7, 2018

Prior Authorization Required ✓ Type of Review – Care Management ✓ Type of Review – Clinical Review

Not Covered

Pharmacy (RX) or Medical (MED) Benefit MED Department to Review MM / PRECERT

This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

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: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**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 requesting physician is an asthma specialist (allergist, immunologist, or pulmonologist)
3. The requesting physician has documented that the Member has had a failure of a treatment regimen that included inhaled corticosteroids, oral corticosteroids, leukotriene modifiers and inhaled long-acting bronchodilators, or has a contraindication to / is unable to tolerate these medications
Examples of asthma treating products:

<table>
<thead>
<tr>
<th><strong>Inhaled Corticosteroids</strong></th>
<th><strong>Oral Corticosteroids</strong></th>
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</thead>
<tbody>
<tr>
<td>• Asmanex® (mometasone furoate)</td>
<td>• methylprednisolone</td>
</tr>
<tr>
<td>• Flovent® HFA (fluticasone propionate)</td>
<td>• prednisone</td>
</tr>
<tr>
<td>• QVAR® (beclomethasone dipropionate HFA)</td>
<td>• prednisolone</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th><strong>Long-Acting Bronchodilator</strong></th>
<th><strong>Leukotriene Modifiers</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Foradil® Aerolizer (formoterol fumarate)</td>
<td>• montelukast (Singulair®)</td>
</tr>
<tr>
<td>• Serevent® Diskus (salmeterol xinafoate)</td>
<td>• zafirlukast (Accolate®)</td>
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<table>
<thead>
<tr>
<th><strong>Combination Long-Acting Bronchodilator and Corticosteroid</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Advair® (fluticasone/salmeterol)</td>
</tr>
<tr>
<td>• Symbicort® (budesonide/formoterol fumarate)</td>
</tr>
</tbody>
</table>

4. Member shows a definitive sensitivity on allergy testing to one or more perennial allergens  

5. Documentation of a pre-treatment serum IgE level of:  
   - Members ≥12 years: ≥30 IU/mL and ≤700 IU/mL  
   - Members 6-11 years of age: ≥30 IU/mL and ≤1,300 IU/mL

**Chronic Idiopathic Urticaria (CIU)**

1. The Member is ≥12 years of age  

2. The Member has a definitive diagnosis of CIU for at least 6 weeks  

3. The requesting physician is an allergist, dermatologist or immunologist  

4. The requesting physician has documented that the Member remains symptomatic in spite of at least 2 weeks of treatment with a trial of each of the following regimens or documented history of contraindication or intolerance to:  
   - H₁ plus H₂-antihistamine  
   - H₁-antihistamine plus a leukotriene receptor antagonist  

5. The Member is being treated concurrently with an H₁-antihistamine unless contraindicated or intolerance exists  

6. Documentation of medical evaluation for other causes of the urticaria

**LIMITATIONS**

1. 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 Pharmacy Coverage 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) or less than 12 years of age (chronic idiopathic urticaria).  

2. 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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2357</td>
<td>Injection, omalizumab, 5 mg</td>
</tr>
</tbody>
</table>

**REFERENCES**


**APPRAOHS HISTORY**

December 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- December 14, 2004: Add “oral corticosteroids” to criteria #2
- December 13, 2005: No changes
- November 4, 2006: Change title from “Xolair (omalizumab) for the Treatment of Moderate to Severe Persistent Asthma” to “Xolair (omalizumab)”
- November 13, 2007: Updated examples of asthma treating products.
- November 11, 2008: No changes.
- November 10, 2009: Updated examples of asthma treating products.
- January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
- November 9, 2010: No changes.
- November 15, 2011: No changes.
- November 6, 2012: No changes.
- October 15, 2013: No changes.
- January 13, 2015: Removed disease severity score submission requirement for diagnosis of CIU.
- January 1, 2016: Administrative change to rebranded template.
- February 9, 2016: No changes.
- July 12, 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. Added contraindication language to prerequisites for severe persistent asthma.
April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
July 11, 2017: No changes
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 ≤1,300 IU/mL. Members ≥12 years of age will continue to require pre-treatment levels of ≥30 IU/mL and ≤700 IU/mL.
August 7, 2018: No changes

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.