Pharmacy Medical Necessity Guidelines: Xolair® (omalizumab)

Effective: February 15, 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:

Commercial Products
PRECERT: 617.972.9409

Tufts Health Public Plans Products
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.
- **Nasal Polyps**
  Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

COVERAGE GUIDELINES

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

Allergic Asthma

Initial Therapy

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

AND

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

AND

3. Member is at least 6 years of age

AND

4. Prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, or pulmonologist)

AND

5. Documentation of poor asthma control or recurrent exacerbations requiring additional treatment despite an adherent trial of at least 3-month duration of a medium to high-dose inhaled corticosteroid in combination with a long-acting inhaled beta-2 agonist (LABA), leukotriene modifier, or theophylline or the Member is intolerant or has a contraindication to all of these medications

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

Reauthorization Criteria

1. Documentation of moderate to severe persistent asthma

AND

2. Member is at least 6 years of age

AND

3. Prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, or pulmonologist)

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least one 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 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

Chronic Idiopathic Urticaria (CIU)

Initial Therapy

1. Documented diagnosis of chronic idiopathic urticaria defined by presence of the condition for at least 6 weeks

AND

2. Member is at least 12 years of age

AND

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

AND

4. Documentation the Member is symptomatic despite an adherent trial of at least 2 weeks duration of a H1 plus H2-antihistamine or H1-antihistamine plus a leukotriene receptor antagonist, or the Member is intolerant or has a contraindication to all of these medications

Reauthorization Criteria

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, dermatologist or immunologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by at least one of the following:
    a. Reduced itching
    b. Reduction in the number and/or size of hives

Nasal Polyps

Initial Therapy

1. Documented diagnosis of nasal polyps

AND

2. Member is at least 18 years of age

AND

3. The prescribing physician is an allergist, immunologist, or otolaryngoloist

AND

4. Documentation of poor control requiring additional treatment despite adherent ≥3 month trial of an intranasal corticosteroid in combination with a leukotriene modifier

AND

5. Documentation of **one (1) of the following:**
    a. Member is concurrently treated with intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

Reauthorization Criteria

1. Documented diagnosis of nasal polyps

AND

2. Member is at least 18 years of age

AND

3. The prescribing physician is an allergist, immunologist, or otolaryngologist

AND

4. Documentation of one of the following:
    a. Member is concurrently treated with intranasal corticosteroids
    b. Contraindication to intranasal corticosteroids

AND

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

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 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).

- 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)
- Initial approval will be limited to 6 months. Reauthorization of Xolair (omalizumab) will be provided in 12-month intervals.
- Members new to the plan stable on Xolair (omalizumab) should be reviewed against Reauthorization Criteria for all indications.

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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10. Holgate S, Bousquet J, Wenzel S, Fox H, Liu J, Castellsague J. Efficacy of omalizumab, an antiimmunoglobulin 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.
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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.
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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.; Dec 2020.

APPROVAL HISTORY

December 2003: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. December 14, 2004: Add "oral corticosteroids" to criteria #2
2. December 13, 2005: No changes
3. November 14, 2006: Change title from "Xolair (omalizumab) for the Treatment of Moderate to Severe Persistent Asthma" to "Xolair (omalizumab)"
4. November 13, 2007: Updated examples of asthma treating products.
5. November 11, 2008: No changes.
6. November 10, 2009: Updated examples of asthma treating products.
7. January 1, 2010: Removal of Tufts Health Plan Medicare Preferred language (separate criteria have been created specifically for Tufts Health Plan Medicare Preferred).
8. November 9, 2010: No changes.
9. November 15, 2011: No changes.
10. November 6, 2012: No changes.
11. October 15, 2013: No changes.
12. June 10, 2014: Added pharmacy coverage guidelines for the Diagnosis of Chronic Idiopathic Urticaria (CIU). Added approval limitations and timelines.
13. January 13, 2015: Removed disease severity score submission requirement for diagnosis of CIU.
14. January 1, 2016: Administrative change to rebranded template.
15. February 9, 2016: No changes.
16. 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.
17. April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
18. July 11, 2017: No changes
19. 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.
20. August 7, 2018: No changes
21. September 10, 2019: No changes
22. October 15, 2019: For chronic idiopathic urticaria, updated coverage criteria to require trial of at least one of the following regimens: H_1 plus H_2-antihistamine or H_1-antihistamine plus a leukotriene receptor antagonist.
23. April 14, 2020: Effective July 1, 2020, Medical Necessity Guideline applies to Tufts Health Together and Tufts Health RITogether. Modified reauthorization criteria for all indications and added the following Limitation: Members new to the plan stable on Xolair should be reviewed against Reauthorization Criteria. For allergic asthma, removed the upper limits of baseline IgE levels, changed the provider specialty requirement to "Prescribed by or in consultation with an asthma specialist (e.g., allergist, immunologist, or pulmonologist).", and changed the criteria to require "Documentation of poor asthma control or recurrent exacerbations requiring additional treatment despite an adherent trial of at least 3-month duration of a medium to high-dose inhaled corticosteroid in combination with a long-acting inhaled beta-2 agonist (LABA), leukotriene modifier, or theophylline or the Member is intolerant or has a contraindication to all of these medications." Added the following Limitation: "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." Changed the duration of initial authorizations to 6 months.
24. December 8, 2020: Effective January 1, 2021, Tufts Health Together removed from the Medical Necessity Guideline.
25. February 9, 2021: Added coverage criteria for the supplemental indication of nasal polyps.

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.