Pharmacy Medical Necessity Guidelines:
Xolair® (omalizumab) Pre-filled Syringe for Self-administration

Effective: September 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RxUM:617.673.0939	

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

OVERVIEW

FOOD AND DRUG ADMNISTRATION-APPROVED INDICATIONS

Xolair (omalizumab) prefilled syringe for self-administration is an anti-IgE antibody indicated for:

- **Allergic Asthma**

Patients six (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.

- **Chronic Idiopathic Urticaria**

Patients 12 years of age and older with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment.

- **IgE-Mediated Food Allergy**

The reduction of allergic reaction (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods in adult and pediatric patients aged 1 year and older with IgE-mediated food allergy. Xolair is to be used in conjunction with food allergen avoidance.
Limitations of Use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis

- **Chronic Rhinosinusitis with Nasal polyps**

Add-on maintenance treatment of chronic rhinosinusitis with 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 pre-filed syringe for self-administration for Members when **ALL** of the following criteria are met:

Allergic Asthma

Initial Authorization Criteria

1. Documentation of **one (1)** of the following:
    a. Diagnosis of moderate to severe persistent asthma
    b. Current treatment with an alternative biologic indicated for moderate to severe asthma

AND

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

AND

3. Documentation of a positive skin test or in vitro reactivity to at least one perennial allergen

AND

4. Patient is at least 6 years of age or older

AND

5. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

6. Documentation the patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist

AND

7. Documentation the patient will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of moderate to severe persistent asthma

AND

2. Patient is at least 6 years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** 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 corticosteroids to treat and/or prevent asthma exacerbations

AND

5. The patient will not be concurrently treated with an alternative biologic for asthma

Chronic Idiopathic Urticaria

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe chronic idiopathic urticaria defined by presence of the condition for at least six (6) weeks

AND

2. Patient is at least 12 years of age or older

AND

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

AND

4. Documentation of **one (1)** of the following:
    a. Patient remains symptomatic despite treatment with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine)
    b. Contraindication to second-generation H1 antihistamines

Reauthorization Criteria

1. Documented diagnosis of moderate to severe chronic idiopathic urticaria

AND

2. Patient is at least 12 years of age or older

AND

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

AND

4. Documentation the patient has experienced a therapeutic response as defined by one (1) of the following:
    a. Reduced itching
    b. Reduction in the number and/or size of hives

IgE-Mediated Food Allergy

Initial Authorization Criteria

1. Documentation of one (1) of the following:
    a. Both of the following:
        i. Documented diagnosis of IgE mediated food allergy as evidence by one of the following:
            1. Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food
            2. Positive food specific IgE (greater than or equal to 6 kUA/L)

3. Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein

ii. Clinical history of IgE mediated food allergy

b. Provider attestation that the patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

2. Patient is at least 1 year of age or older

AND

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

AND

4. Documentation of use in conjunction with food allergen avoidance

AND

5. Documentation of both of the following:
   a. Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL
   b. Dosing is according to serum total IgE levels and body weight

Reauthorization Criteria

1. Documented diagnosis of Ig-E mediated food allergy

AND

2. Prescribed by or in consultation with an allergist or immunologist

AND

3. Patient is at least 1 year of age or older

AND

4. Documentation of use in conjunction with food allergen avoidance

AND

5. Documentation the dose will continue to be based on body weight and pre-treatment total IgE serum levels

AND

6. Documentation the patient has experienced a therapeutic response to therapy

Chronic Rhinosinusitis with Nasal Polyps

Initial Authorization Criteria

1. Documented diagnosis of nasal polyps

AND

2. Patient is at least 18 years of age or older

AND

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

AND

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

AND

5. The patient will not be concurrently treated with an alternative biologic for nasal polyps

Reauthorization Criteria

1. Documented diagnosis of nasal polyps

AND

2. Patient is at least 18 years of age or older

AND

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

AND

4. Documented of **one (1)** of the following:
   a. Patient is concurrently treatment intranasal corticosteroids
   b. Contraindication to intranasal corticosteroids

AND

5. Document the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
    a. Adequate sinus ventilation and drainage
    b. Control of mucosal inflammation and edema
    c. Reduction in exacerbations

AND

6. The patient will not be concurrently treated with an alternative biologic for nasal polyps

LIMITATIONS

- Initial approval of Xolair will be authorized for six (6) months. Reauthorization of Xolair will be provided in 12-month intervals.
- Patients new to the plan stable on Xoliar should be reviewed against Reauthorization Criteria.

CODES

None

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APPROVAL HISTORY

September 13, 2023: Reviewed by Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- May 14, 2024: Added coverage criteria for the supplemental indication of Ig-E Mediated Food Allergy. For asthma, updated diagnosis requirements to include current treatment with another biologic for moderate to severe asthma. For nasal polyps, removed documentation of one of the following: Patient remains symptomatic despite treatment with an intranasal corticosteroid or contraindication to intranasal corticosteroids. Removed documentation of one of the following: prior treatment of nasal polyps with systemic corticosteroids within the past two years, contraindication to systemic corticosteroids or prior nasal polyp removal surgery (eff 6/1/24)
- May 13, 2025: No changes (eff 5/13/25).
- June 9, 2026: Updated duration of approval rules to be initial 6 months and 12 months for reauthorization for all indications (eff 9/1/26).

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.

Provider Services