Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:

Xolair (omalizumab) Pre-filled Syringe and Autoinjector

Effective: September 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Xolair (omalizumab) Prefilled Syringe and Autoinjector is an anti-IgE antibody indicated for:

- **Asthma**
  Adults and pediatric 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. Xolair is not indicated for relief of acute bronchospasm or status asthmaticus.
- **Chronic Spontaneous Urticaria**
  The treatment of adults and adolescents 12 years of age and older with chronic spontaneous 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. 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Xolair pre-filled syringe and autoinjector for Members when **ALL** of the following criteria are met:

Asthma

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of moderate to severe persistent allergic asthma with **both** of the following:
   a. Positive skin test or in vitro reactivity to at least one perennial allergen
   b. Pre-treatment serum immunoglobulin E level greater than or equal to 30 international units per milliliter

AND

2. Patient is 6 (six) years of age or older

AND

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

AND

4. Documentation of **one (1)** of the following within the previous 12 months:
   a. History of two (2) or more asthma exacerbations requiring systemic corticosteroids

b. Prior asthma-related hospitalizations

AND

5. Documentation of history of failure to a minimum three (3) month trial with 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), unless contraindicated

AND

6. Documentation the requested medication will be used as add-on maintenance therapy with 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), unless contraindicated

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin 4 therapy (e.g., dupilumab)
    b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Reauthorization Criteria

1. Documented diagnosis of moderate to severe persistent allergic asthma

AND

2. Patient is six (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. Documentation the requested medication will be used as add-on maintenance therapy with a maximally tolerated inhaled corticosteroid plus at least one other asthma medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist), unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin 4 therapy (e.g., dupilumab)
    b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Chronic Spontaneous Urticaria

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic spontaneous urticaria

AND

2. Documentation of persistent symptoms of chronic spontaneous urticaria for at least six (6) weeks despite use of a second generation H1 antihistamine, unless contraindicated

AND

3. Patient is 12 years of age or older

AND

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

AND

5. Documentation of history of failure to a minimum two (2) week trial with a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine), unless contraindicated

AND

6. Documentation the requested medication will be used concurrently with a second-generation H1 antihistamine, unless contraindicated

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:

a. Anti-interleukin 4 therapy (e.g., dupilumab)
b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Reauthorization Criteria

1. Documented diagnosis of chronic spontaneous urticaria

AND

2. Patient is 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

AND

5. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin 4 therapy (e.g., dupilumab)
   b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
   c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

IgE-Mediated Food Allergy

Initial Authorization Criteria

1. Submission of medical charts documenting **one (1)** of the following:
   a. Diagnosis of IgE mediated food allergy as evidenced by clinical history of IgE mediated food allergy and **one (1)** of the following:
      i. Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food
      ii. Positive food specific IgE (greater than or equal to 6 kUA/L)
      iii. 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
   b. Patient history of severe allergic response, including anaphylaxis, following exposure to one or more foods

AND

2. Patient is one (1) year old or older

AND

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

AND

4. Documentation the requested medication will be used 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 international units per milliliter
   b. Dosing is according to serum total IgE levels and body weight

AND

6. Documentation the requested medication will not be used for the emergency treatment of allergic reactions, including anaphylaxis

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
   a. Anti-interleukin 4 therapy (e.g., dupilumab)
   b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
   c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

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 one (1) year of age or older

AND

4. Documentation the requested medication will be used 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 requested agent will not be used for the emergency treatment of allergic reactions, including anaphylaxis

AND

7. Documentation the patient has experienced a clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

8. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin 4 therapy (e.g., dupilumab)
    b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Chronic Rhinosinusitis with Nasal Polyps

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Documentation of history of failure to a minimum eight (8) week trial of intranasal corticosteroids, unless contraindicated

AND

5. Documentation the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin 4 therapy (e.g., dupilumab)
    b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Reauthorization Criteria

1. Documented diagnosis of chronic rhinosinusitis with nasal polyps

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Documentation the requested medication will be used as add-on maintenance therapy with intranasal corticosteroids, unless contraindicated

AND

5. Documentation 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. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin 4 therapy (e.g., dupilumab)
    b. Anti-interleukin-5 therapy (e.g., benralizumab, mepolizumab, reslizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)

Limitations

1. Initial approval of Xolair pre-filled syringe and autoinjector will be authorized for six (6) months. Reauthorization of Xolair pre-

filled syringe and autoinjector will be provided in 12-month intervals.

2. Members new to the plan stable on Xolair pre-filled syringe and autoinjector should be reviewed against Reauthorization Criteria. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization Criteria.

Codes

None

References

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Approval And Revision History

September 13, 2022: Reviewed by the 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 (eff 6/1/24)
- May 13, 2025: No changes (eff 5/13/25).
- June 9, 2026: Removed the Limitation For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated. For Asthma added submission of medical charts confirming diagnosis (Initial), removed current treatment with an alternative respiratory biologic as confirmation of diagnosis (Initial), added severity requirements (history of exacerbations or hospitalization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), added confirmation treatment will be used as add-on therapy (Reauthorization), and added submission of medical charts confirming objective reauthorization criteria (Reauthorization). For CSU added submission of medical charts confirming diagnosis (Initial), added antihistamine step (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), added confirmation treatment will be used as add-on therapy (Initial), added concurrent therapy language (Initial and Reauthorization), and added submission of medical charts confirming objective reauthorization criteria (Reauthorization). For IgE-medicated Food Allergy added submission of medical charts confirming diagnosis with existing clinical criteria (Initial); added confirmation of non-emergency use (Initial and Reauthorization); added concurrent therapy language (Initial and Reauthorization); added medication will not be used for the emergency treatment of allergic reactions, including anaphylaxis (Initial and Reauthorization); added submission of medical charts confirming broad reauthorization criteria (Reauthorization); and updated initial approval duration from 5 to 6 months. For Chronic Rhinosinusitis with Nasal Polyps added additional objective responses to therapy in objective reauthorization criteria (Reauthorization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), and submission of medical charts confirming objective reauthorization criteria (Reauthorization). Added limitation statement that members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria. Administrative update to remove CareLink from the Medical Necessity Guideline template (eff 9/1/26).
- August 11, 2026: Removed submission of medical records requirements for response to therapy in Reauthorization Criteria (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.