STATE OF WEST VIRGINIA
DEPARTMENT OF HUMAN SERVICES
BUREAU FOR MEDICAL SERVICES

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# Office of Pharmacy Services
# Prior Authorization Criteria
# Xolair® (Omalizumab)

**Prior Authorization Request Form**

***Effective 09/25/2024***

*Xolair is an anti-IgE antibody indicated for:*

- *Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.*
- *Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.*
- *Add-on maintenance treatment of nasal polyps in adults with inadequate response to nasal corticosteroids*
- *IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance*

***Prefilled syringes are non-preferred and require class criteria to be met prior to approval. Class criteria requires the trial of each preferred agent that is indicated for the requested diagnosis (please see the updated PDL for preferred options). In addition, prefilled syringes may only be approved if determined appropriate by the medical provider AND the member or caregiver will be the individual administering Xolair.* Candidates for self-administration must have previously received at least 3 doses of Xolair.**

**Prior authorization requests for Xolair may be approved if the following criteria are met:**

**For moderate to severe persistent asthma:**

1) Patient is six (6) years of age or older; **AND**
2) Must be prescribed by a board-certified pulmonologist or board-certified allergist; **AND**
3) Current body weight is between 20kg and 150kg; **AND**
4) If the patient currently smokes they must be enrolled in a smoking cessation program; **AND**
5) Patient is symptomatic despite receiving recommended first line treatments (including high dose inhaled corticosteroids + LABA) and exhibiting compliance with those treatments; **AND**
6) Patient has reacted positively to a perennial aeroallergen skin or blood test; **AND**

7) Patient must have an IgE level not less than 30 IU/ml or more than the Manufacturer's recommendation, based on weight. (The patient's weight and pretreatment serum IgE must be presented to review dosing).

**For moderate to severe Chronic Idiopathic Urticaria:**

1. Current diagnosis must be Chronic Idiopathic Urticaria, (documentation supporting diagnosis must be provided with PA request); **AND**
2. Patient must be twelve (12) years of age or older; **AND**
3. Prescribed written by a board-certified Allergist, Immunologist, or Dermatologist; **AND**
4. Patient must have documented failure of 60-days of therapy with a 2nd-generation H1 antihistamine prescribed at 2x – 4x the usual dose*;* **AND**
5. At least 30 days of therapy using a combination of a 2nd-generation H1 antihistamine (prescribed at 2x – 4x the usual dose) concurrent with one or more of the following treatment options:
    *a.* Add a different 2nd-generation H1 antihistamine
    *b.* Add an H2 antihistamine
    *c.* Add a 1st generation antihistamine at night
    *d.* Add montelukast (or other leukotriene receptor antagonist).
    *e.* Add high-potency antihistamine hydroxyzine or doxepin and titrate as tolerated
6. Patients who do not tolerate at least 2x the normal listed dose of the 2nd generation H1 antihistamines (see below) will be required to try each agent (and possibly combinations of these agents) until they either tolerate one of them to the required dosing range or they have documented intolerance to all of them.

**For treatment of nasal polyps:**

1. Must be prescribed by or in consultation with, an ENT, allergist, or other suitable specialist; **AND**
2. The patient must have a diagnosis of nasal polyps which has been inadequately controlled after at least 3-months of therapy with any intranasal steroid; **AND**
3. The patient must be within the approved age range according to the FDA label and indication; **AND**
4. Xolair is only approvable as add-on therapy for nasal polyps.

Continuation of coverage requires documentation of reduction/elimination of nasal polyps AND patient adherence to therapy (including the original agent Xolair was supplementing).

**For IgE-mediated food allergy:**

1. Patient is one year of age or older; **AND**
2. Must be prescribed by, or in consultation with a M.D./D.O. allergist or immunologist; **AND**
3. Patient is allergic to peanuts **AND** at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut; **AND**
4. Documentation (reports with results) is provided of the following:
    a. Positive skin prick test (≥4 mm wheal) to above foods; **and**
    b. Positive food specific IgE (≥6 kUA/L) to above foods at screening or within three months of screening; **or**
    c. Positive DBPCFC (food challenge) to above foods, defined as experiencing dose-limiting symptoms at a single dose of ≤ 100mg of peanut protein and ≤300 mg of food protein; **AND**
5. Baseline serum IgE level equal to or greater than 30 IU/mL; **AND**
6. The patient has a history of a severe (type 1) allergic reaction requiring an ER visit, or hospitalization **AND** they had a history of wheeze, angioedema, and/or hives/urticaria; **AND**
7. This reaction occurred within a short period of time following a known ingestion of the food; **AND**

8. The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector and has prescribed one; **AND**
9. Xolair will be used in conjunction with a food allergen avoidance diet; **AND**
10. The patient is not on another monoclonal antibody.

**CONTINUATION OF THERAPY CRITERIA:**

1. Patient continues to meet all initial approval criteria; **AND**
2. Demonstrate continued documented compliance.

***Xolair may be initially approved for 90 days. Continuation of therapy approvals may be approved for 1 year after criteria has been met.***

## SUMMARY OF STEP THERAPY REQUIREMENTS FOR TREATMENT OF CIU

A minimum 60 days of therapy is required before Xolair is approvable

**Step 1**

Start 2nd-gen $H_1$ antihistamine and titrate to 2x-4x the usual dose.

Insufficient improvement while using 2x – 4x the usual dose of any 2nd generation H1 antihistamine for at least 30 days.

**Step 2**

Combine one or more of the following with the maximized dose of the H1 antihistamine from Step 1:

- Add a different 2nd-generation H1 antihistamine
- Add an H2 antihistamine
- Add a 1st generation antihistamine at night
- Add montelukast (or other leukotriene receptor antagonist).
- Add high-potency antihistamine hydroxyzine or doxepin and titrate as tolerated

Usual doses of the second-generation H1 blockers:

Cetirizine 10 mg QD-bid
Desloratadine 5 mg QD
Fexofenadine 180 mg QD-bid
Levocetirizine 5 mg QD-bid
Loratadine 10 mg QD-bid

Insufficient improvement after at least 30 days of combination therapy.

Prior authorization granted for 3 months. An additional 12 months may be authorized with documentation of satisfactory clinical improvement