



## Montana Healthcare Programs Drug Prior Authorization (PA) and Physicians Administered Drug (PAD) Coverage Criteria **XOLAIR® (omalizumab)**

### I. Medication Description

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 inadequately controlled with inhaled corticosteroids.
- Chronic spontaneous urticaria (previously called chronic idiopathic urticaria) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Chronic rhinosinusitis with nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids as add-on maintenance treatment.
- 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.

### II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

### III. Initial Coverage Criteria

#### Allergic Asthma:

Member must meet all the following criteria:

- Be 6 years of age or older.
- Have a diagnosis of moderate to severe persistent asthma **AND** a positive skin test or in vitro reactivity to a perennial aeroallergen.
- Have an inadequate treatment response, intolerance, or contraindication to maximized treatment with an inhaled corticosteroid (ICS) which has been used adherently for 3 months.
- Had a trial and inadequate response, or contraindication to a preferred drug with the same indication from the Montana Healthcare Programs Preferred Drug List [19dur](#) (unless preferred product[s] do not have the appropriate indication).

Prescriber requirements:

- Must be prescribed by or in consult with an allergy, pulmonology or immunology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must submit pretreatment serum total IgE level and current body weight for dose verification.

- Attests to the following:
  - Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a health care setting and only appropriate patients will be allowed to self-administer.
  - Concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be used concomitantly.

### **Chronic Spontaneous Urticaria (CSU):**

Member must meet all the following criteria:

- Be 12 years of age or older.
- Have a diagnosis of chronic spontaneous urticaria (also called chronic idiopathic urticaria).
- Member must have had an inadequate response to 2 different H1 antihistamine trials of 4 weeks each.

Prescriber requirements:

- Must be prescribed by or in consult with an allergy, dermatology or immunology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Attests to the following:
  - Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a health care setting and only appropriate patients will be allowed to self-administer.
  - Concomitant use of Xolair® with immunosuppressive therapy has not been evaluated and will not be prescribed.

### **Chronic Rhinosinusitis with Nasal Polyposis:**

Member must meet all the following criteria:

- Be 18 years of age or older.
- Have a diagnosis and clinical documentation of chronic rhinosinusitis WITH nasal polyps as evidenced by CT scan or endoscopy.
- Have an inadequate treatment response, intolerance or contraindication to:
  - One intranasal corticosteroid which has been used adherently and at optimized doses for 3 months **AND**
  - Systemic corticosteroid trial within the last year **OR** sino-nasal surgery.
- Must concurrently be using an intranasal corticosteroid, unless contraindicated.

Prescriber requirements:

- Must be prescribed by or in consult with an allergy, immunology or otolaryngology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Must submit pretreatment serum total IgE level and current body weight for dose verification.
- Attests to the following:

- Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a healthcare setting and only appropriate patients will be allowed to self-administer.
- Concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.

**IgE-Mediated Food Allergy:**

Member must meet all the following criteria:

- Be 1 year of age or older.
- Have a diagnosis IgE-mediated food allergy (Type I) to one or more foods.

Prescriber requirements:

- Must be prescribed by or in consult with an allergy or immunology specialty clinic.
- If not prescribed by an appropriate specialist, a copy of the specialty consult is required. Annual consult required for yearly reauthorization.
- Has placed member on a food allergen avoidance program.
- Must submit pretreatment serum total IgE level and current body weight for dose verification.
- Attests to the following:
  - Due to the boxed warning risk of anaphylaxis, Xolair® will be initiated in a health care setting and only appropriate patients will be allowed to self-administer.
  - Concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.

Limitations: Dosed per labeling based on IgE and weight.

**IV. Renewal Coverage Criteria**

**Allergic Asthma:**

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Has been adherent to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

**CSU:**

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Has been adherent to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests concomitant use of Xolair® with immunosuppressive therapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

### **Chronic Rhinosinusitis with Nasal Polyposis:**

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Has been adherent to therapy: Xolair® and intranasal corticosteroid.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

### **IgE-Mediated Food Allergy:**

Member must meet all the following criteria:

- Has documentation of positive clinical response to therapy (reduction in the frequency and/or severity of symptoms and exacerbations).
- Has been adherent to therapy.

Prescriber requirements:

- Annual specialist consult provided if prescriber not a specialist.
- Attests that concomitant use of Xolair® and allergen immunotherapy has not been evaluated and will not be prescribed.
- Verification of compliance will be made via Medicaid paid claims data. If non-compliance is determined, the reauthorization time frame may be reduced to allow time for the provider to address member compliance.

## **V. Quantity Limits**

Maximum daily dose:

- Allergic Asthma: 375 mg every 2 weeks.

- CSU: 300 mg every 4 weeks.
- Chronic Rhinosinusitis with Nasal Polyposis: 600 mg every 2 weeks.
- IgE-Mediated Food Allergy: 600 mg every 2 weeks

## VI. Coverage Duration

### Initial approval:

- Allergic Asthma: 12 months
- CSU: 3 months
- Chronic Rhinosinusitis with Nasal Polyposis: 6 months
- IgE-Mediated Food Allergy: 6 months

### Renewal approval duration:

- Allergic Asthma: 12 months
- CSU: 6 months
- Chronic Rhinosinusitis with Nasal Polyposis: 12 months
- IgE-Mediated Food Allergy: 12 months

### References:

#### Xolair

[https://www.xolairhcp.com/?utm\\_source=google&utm\\_medium=cpc&utm\\_campaign=2024\\_Xolairhcp.com%20HCP%20Branded;S;PH;BR;RES;HCP;BR&utm\\_content=Administration%20Injection&utm\\_term=injection%20xolair%20information&gclid=CjwKCAjw8diwBhAbEiwA7i\\_sJQuTfvDdnwYXsNiC7Bp\\_UgIc20ew4mrzJ608FCZxwHdfU7HmG1JiaRoCrBYQAvD\\_BwE](https://www.xolairhcp.com/?utm_source=google&utm_medium=cpc&utm_campaign=2024_Xolairhcp.com%20HCP%20Branded;S;PH;BR;RES;HCP;BR&utm_content=Administration%20Injection&utm_term=injection%20xolair%20information&gclid=CjwKCAjw8diwBhAbEiwA7i_sJQuTfvDdnwYXsNiC7Bp_UgIc20ew4mrzJ608FCZxwHdfU7HmG1JiaRoCrBYQAvD_BwE)

Chronic urticaria (CU) is defined as urticaria present continuously or intermittently (present on most days of the week) for at least 6 weeks. CU may be divided into chronic inducible urticaria, also known as physical urticaria, and **chronic spontaneous urticaria (CSU)**, previously recognized as **chronic idiopathic urticaria**. CSU is defined as the spontaneous appearance of wheals, angioedema, or both for at least 6 weeks from unknown causes.<sup>1</sup>

1. Johal, Kirti J, MD, Saini, Sarbjit, MD; Current and Emerging Treatment for Chronic Spontaneous Urticaria; published: September 5,2019 Annals of Allergy, Asthma & Immunology  
[https://www.annallergy.org/article/S1081-1206\(19\)31054-3/fulltext](https://www.annallergy.org/article/S1081-1206(19)31054-3/fulltext)