ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

# UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

**CONTAINS CONFIDENTIAL PATIENT INFORMATION**

**Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538**

☐ **Urgent**[1] ☐ **Non-Urgent**

**Requested Drug Name: Xolair® (omalizumab)**

| **Patient Information:** | **Prescribing Provider Information:** |
|---|---|
| Patient Name: | Prescriber Name: |
| Member/Subscriber Number: | Prescriber Fax: |
| Policy/Group Number: | Prescriber Phone: |
| Patient Date of Birth (MM/DD/YYYY): | Prescriber Pager: |
| Patient Address: | Prescriber Address: |
| Patient Phone: | Prescriber Office Contact: |
| Patient Email Address: | Prescriber NPI: |
| | Prescriber DEA: |
| Prescription Date: | Prescriber Tax ID: |
| | Specialty/Facility Name (If applicable): |
| | Prescriber Email Address: |

**Prior Authorization Request for Drug Benefit:** ☐ New Request ☐ Reauthorization

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

**Xolair® (omalizumab)**

**Diagnosis (documentation supportive of diagnosis is required)**

☐ IgE-mediated allergic asthma (documentation required)
☐ Chronic Idiopathic urticaria (documentation required)
☐ Other (please state): _____

**Clinical Consideration (for approval, please indicate and provide documentation of the following):**

***For IgE-mediated allergic asthma***
☐Pulmonary function testing has confirmed reversible airway disease (12% or greater FEV1 improvement or 20% or greater PEF improvement) **AND**
☐ Positive skin test or blood test to confirm allergic sensitivity **AND**
☐ Moderate to severe persistent asthma inadequately controlled despite high dose inhaled steroids

Patient weight: _____
IgE level: _____ *(IgE must be between 30 IU/mL and 700 IU/mL)*
Date drawn: _____

***For Chronic Idiopathic Urticaria***

☐ H1-antihistamine refractory ***(documentation of continued symptoms despite H1 antihistamine therapy required)***

**Please note:** For CHRONIC IDIOPATHIC URTICARIA, INITIAL APPROVAL WILL BE FOR ONE MONTH and if patient responds to therapy, re-approvals will be granted in 12 month increments. Plan accordingly and be able to provide documentation of outcome to RMHP to prevent delay in therapy.

***For both conditions:***

☐ Patient ≥12 years of age
☐ **Renewal Request:** Submit medical records documenting therapy success.

**Physician Specialty**

☐ **Allergy**
☐ **Pulmonology**
☐ **Other (please state):** _____

☐ For use in clinical trial? (If yes, provide trial name and registration number):

Drug Name (Brand Name and Scientific Name)/Strength:

| Dose: | Route: | Frequency: |
|---|---|---|
| Quantity: | Number of Refills: | |

Product will be delivered to: ☐ Patient's Home ☐ Physician Office Other:

**Prescriber or Authorized Signature:** Date:

Dispensing Pharmacy Name and Phone Number:

☐ **Approved** ☐ **Denied**

If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:

1. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request

**RMHP Formulary Coverage Policy**

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

# Xolair® (olamizumab)

## CLASSIFICATION

- Anti-asthma, monoclonal antibody

## DESCRIPTION

- Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (RI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on RI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with omalizumab also reduces the number of RI receptors on basophils in atopic patients.
- The intravenous route of administration is not approved by the U.S. FDA.

**IgE-mediated allergic asthma:**

- Omalizumab is indicated in patients age 12 years or older with symptoms of moderate to severe persistent asthma not controlled by inhaled corticosteroids and who have a positive skin test or in vitro reactivity to a perennial aeroallergen.
- Omalizumab is not indicated for acute bronchospasm, status asthmaticus, or for other allergic conditions.
- Omalizumab is recommended as an adjunct in patients with severe persistent asthma who are inadequately controlled with combination of high-dose inhaled corticosteroids and long-acting beta-agonist and concurrently have allergies (National Heart,Lung,and Blood Institute: Expert panel report 3: guidelines for the diagnosis and management of asthma. National Heart,Lung,and Blood Institute. Bethesda, MD. 2007.).
- In a 48-week, prospective, randomized, double-blind trial (n=848) omalizumab-treated patients (age range, 12 to 75 years) experienced a significant 25% relative reduction in the asthma exacerbation rate compared with placebo in patients with severe allergic asthma inadequately controlled on high-dose inhaled corticosteroids and long acting beta agonists with or without other controllers, including oral corticosteroids.
- In a 52-week international, multicenter, randomized, double-blind, placebo-controlled, parallel-group study (n=627), subQ omalizumab was more effective than placebo in children (age 6 to less than 12) with moderate-to-severe allergic asthma, inadequately controlled with medium- to high-dose inhaled corticosteroids.
- Subcutaneous and intravenous omalizumab reduced asthma exacerbations and/or asthma symptoms in patients with moderate to severe persistent asthma inadequately controlled on inhaled corticosteroids; steroid requirements were significantly reduced during omalizumab therapy, although this was not always significant relative to placebo.
- Omalizumab has produced variable results with regards to changes in FEV1.
- Efficacy in allergic asthma has been demonstrated with therapy up to 52 weeks in both adults and children.
- Efficacy of omalizumab has not been compared to inhaled corticosteroids.

**Chronic Idiopathic Urticaria, H1-antihistamine refractory:**

- Omalizumab is indicated for the treatment of chronic idiopathic urticaria in adults and adolescents (12 years or older) who remain symptomatic despite H1 antihistamine therapy.
- In a 24-week, randomized clinical trial (n=319), patients who received omalizumab showed greater improvement in signs and symptoms of chronic idiopathic urticaria compared with placebo. Patients (age range, 12 to 72 years) received either omalizumab 75 mg, 150 mg, 300 mg, or placebo subQ every 4 weeks with baseline H1-antihistamine therapy. At week 12, 36% of

the omalizumab 300-mg group reported absence of itching and hives compared with 15% of omalizumab 150-mg group and 9% of placebo group. After 24 weeks, patients in the omalizumab 150-mg and 300-mg groups had greater decreases in baseline mean weekly itch severity scores (-6.66 and -9.4) and mean weekly hive count scores (-7.78 and -11.35) compared with placebo (-3.63 and -4.37).

- Patients with moderate to severe chronic idiopathic urticaria who received omalizumab 150- and 300-mg doses had greater mean changes from weekly baseline itch severity scores compared with patients who received omalizumab 75 mg or placebo in a randomized trial (n=323). Patients who were symptomatic despite H1-antihistamine therapy at recommended doses were randomized to receive 3 subQ injections every 4 weeks of either omalizumab 300 mg, 150 mg, 75 mg, or placebo followed by a 16-week observation period. H1-antihistamine therapy was permitted during the study period. The mean age was 42.5 years (range, 12 to 75 years) and the mean BMI was 29.8. The change from baseline to week 12 in mean weekly anti-itch scores was significantly reduced in the omalizumab 150-mg group and 300-mg group (-8.1 and -9.8) compared with the placebo group (-5.1).
- Single-dose omalizumab (300 mg or 600 mg) therapy significantly decreased the urticaria activity score over 7 days (UAS7) compared with placebo in patients with chronic idiopathic urticaria refractory to H1 antihistamines in the randomized MYSTIQUE trial (n=90). Following a screening and run-in phase, patients (mean age, 40.8 years) were randomized to receive a single subQ dose of omalizumab 75 mg, 300 mg, or 600 mg, or placebo. At week 4, improvement in the mean change from baseline UAS7 was significantly greater in patients who received omalizumab 300 mg or 600 mg (-19.9 and -14.6) compared with placebo (-6.9). The onset of effect occurred at week 1 and continued throughout the treatment period. Hypersensitivity (including asthma, but not anaphylaxis, injection site reaction, skin rash, or urticaria) occurred in 2 patients (1 in 75-mg and 1 in 600-mg group).

## FORMULARY COVERAGE

Prior authorization: Required
Good Health Formulary: Medical benefit – Tier 6
Commercial Formulary: Medical benefit – Tier 6
Medicare Part D coverage: Tier 5

## COVERAGE CRITERIA

Xolair® (olamizumab) meets the definition of **medical necessity** for the following:

- **IgE-mediated allergic asthma:** Documentation supportive of use in patient 12 years of age or 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, the recommended dose is 150 to 375 milligrams every 2 to 4 weeks. The risk-benefit assessment of omalizumab in patients aged 6 to less than 12 years of age does not support its use in patients less than 12 years of age.
  - Requests meeting criteria are approved in 1-year increments for IgE-mediated allergic asthma.

- **Idiopathic urticaria, chronic, H1 antihistamine-refractory:** Documentation supportive of diagnosis by prescribing provider and H1 antihistamine-refractoriness in patient 12 years of age or older is required.
  - **Please note:** For Chronic Idiopathic Urticaria, INITIAL APPROVAL WILL BE FOR ONE MONTH and if patient responds to therapy, re-approvals will be granted in 12 month increments. Plan accordingly and be able to provide documentation of outcome to RMHP to prevent delay in therapy.

Xolair® (olamizumab) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported including:
  - Treatment of Mild Persistent or Mild Intermittent Asthma
  - Initial treatment of allergic asthma
  - Asthma without baseline pretreatment serum total IgE between 30 IU/ml and 700 IU/ml
  - Allergic rhinitis prophylaxis (seasonal or perennial)
  - Allergy to peanuts (protection)
  - Allergy to latex (protection)
  - Treatment of other allergic conditions or other forms of urticaria.
  - Relief of acute bronchospasm or status asthmaticus.
  - Use in pediatric patients less than 12 years of age.

Required Provider Specialty:

- Approval is limited to Pulmonologist and Allergist

## DOSAGE/ADMINISTRATION:

*Xolair is administered by subcutaneous (SC) injection and should be administered by a healthcare professional. This is due to difficult preparation, dosing variations, and possibility of anaphylaxis.*

- **IgE-mediated allergic asthma, not controlled by inhaled corticosteroids:**
  - For adults and adolescents (12 years or 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, the recommended dose is 150 to 375 mg subQ every 2 to 4 weeks.
  - The manufacturer-recommended dose and dosing frequency are determined by body weight (kilograms) and serum IgE level (international units/milliliter) measured BEFORE start of treatment. Total IgE levels (unbound and complexed) are increased during omalizumab treatment and remain elevated for up to 1 year after discontinuation of treatment. Therefore, after the first dose, serum IgE levels should not be used for dose determination unless treatment has been interrupted for more than 1 year. Subcutaneous dosing is presented in the following table:

| **ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)** | | | | |
|---|---|---|---|---|
| *Pre-treatment Serum IgE (IU/mL)* | *Body Weight (kg)* | | | |
| | 30-60 | 61-70 | 71-90 | 91-150 |
| 30-100 | 150 | 150 | 150 | 300 |
| 101-200 | 300 | 300 | 300 | |
| 201-300 | 300 | | | |
| | | | | |
| **ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)** | | | | |
| *Pre-treatment Serum IgE (IU/mL)* | *Body Weight (kg)* | | | |
| | 30-60 | 61-70 | 71-90 | 91-150 |
| 101-200 | | | | 225 |
| 201-300 | | 225 | 225 | 300 |
| 301-400 | 225 | 225 | 300 | X |
| 401-500 | 300 | 300 | 375 | X |
| 501-600 | 300 | 375 | X | X |
| 601-700 | 375 | X | X | X |
| X = DO NOT DOSE | | | | |

- **Idiopathic urticaria, chronic, H1 antihistamine-refractory:**
  - Usual dose: 150 or 300 mg subQ every 4 weeks; not depending on serum IgE (free or total) level or body weight; appropriate duration of therapy has not been established.

## PRECAUTIONS:

- Black Box Warning: Anaphylaxis presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of omalizumab. Anaphylaxis has occurred as early as after the first dose of omalizumab, but also has occurred beyond 1 year after beginning regularly administered treatment. Because of the risk of anaphylaxis, observe patients closely for an appropriate period of time after omalizumab administration. Health care providers administering omalizumab should be prepared to manage anaphylaxis that can be life-threatening. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur.
- Contraindicated if severe hypersensitivity to omalizumab or any component of the product.
- Acute bronchospasm, acute asthma exacerbations, or status asthmaticus; do not use omalizumab for these indications
- Corticosteroid use (systemic or inhaled); avoid abrupt corticosteroid discontinuation with initiation of omalizumab
- Eosinophilic conditions (e.g. vasculitis consistent with Churg-Strauss syndrome) have been rarely reported, often in association with oral corticosteroid therapy reduction; monitor patients for vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy
- Malignant neoplasms have been reported in both adults and adolescents
- Helminth infections may occur in patients at high risk for geohelminth infections
- Persistent total serum IgE level elevations (i.e., up to 1 year after treatment discontinuation) may impact dosing regimens in allergic asthma patients.
- Serum sickness-like reaction (e.g., fever, arthritis, arthralgia, rash, lymphadenopathy) has been reported 1 to 5 days after at least 1 omalizumab dose. Discontinue if symptoms develop.

## Billing/Coding information

### HCPCS Code:

| | |
|---|---|
| J2357 | injection, omalizumab, 5 mg |

### Associated CPT Coding:

| | |
|---|---|
| 96372 | Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular |

## COST

- AWP (March 2010): 150 mg vial: $694.58
- AWP (January 2012): 150 mg vial: $797.10
- AWP (July 2014): 150 mg vial: $969.71

## COMMITTEE APPROVAL:

- July 2003

## GUIDELINE UPDATE INFORMATION:

| | |
|---|---|
| March 2010 | Policy creation |
| January 2012 | Policy updated |
| July 2014 | Policy updated for Chronic Idiopathic Urticaria indication |

## REFERENCES:


- DRUGDEX®, accessed 03/29/2010, 1/4/12, 7/12/2014
- Product Information: XOLAIR® subcutaneous solution, omalizumab subcutaneous solution. Genentech Inc., South San Francisco, CA, 2007 and 3/2014