

**Complete Patient and Physician information (PLEASE PRINT)**

STEP  
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

If Applicable: Pharmacy Name: \_\_\_\_\_ Pharmacy Phone: \_\_\_\_\_

**Complete the Clinical Assessment:**

**Please attach all relevant medical records and test results**

STEP  
2

Diagnosis	<input type="checkbox"/> Moderate to severe allergic asthma	<input type="checkbox"/> Other (please state): _____
Clinical Consideration	<input type="checkbox"/> Pulmonary function testing has confirmed reversible airway disease (12% or greater FEV1 improvement or 20% or greater PEF improvement)	Patient weight: _____ IgE level: _____ Date drawn : _____
	<input type="checkbox"/> Patient ≥12 years of age	<input type="checkbox"/> Positive skin test or blood test to confirm allergic sensitivity
	<input type="checkbox"/> Severe asthma inadequately controlled despite high dose inhaled steroids	<b>If this is a re-approval request, must submit medical records documenting therapy success</b>
Physician Specialty	<input type="checkbox"/> Allergy <input type="checkbox"/> Pulmonology <input type="checkbox"/> Other (please state): _____	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Xolair <sup>®</sup> (omalizumab)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<b>We will not process incomplete forms. If we do not receive the completed form &amp; all relevant medical records &amp; test results within 10 calendar days of this request, it will be denied.</b>		

STEP  
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete.  
(please sign and date)

\_\_\_\_\_  
Prescriber Signature

\_\_\_\_\_  
Date

STEP  
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk: 970-248-5034**

Name of Person filling out form: \_\_\_\_\_

Pharmacy Technician initials \_\_\_\_\_ Date Initiated \_\_\_\_\_

**Confidentiality Notice:**

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

## RMHP Formulary Coverage Policy

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

### Xolair® (omalizumab)

#### 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.
- Omalizumab is an adjunct in patients with severe persistent asthma who are inadequately controlled with combination of high-dose ICS and long-acting beta-agonist and concurrently have allergies (National Heart, Lung, and Blood Institute, 2007).
- 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 forced expiratory volume in 1 second (FEV1)
- Efficacy in allergic asthma has been demonstrated with therapy up to 52 weeks in both adults and children.
- Subcutaneous omalizumab has been associated with an improvement in quality of life.
- Efficacy has not been compared to inhaled corticosteroids
- The intravenous route of administration is not approved by the U.S. Food and Drug Administration

#### FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Medical benefit (T6)

Commercial Formulary: Medical benefit (T6)

Medicare Part D coverage: Tier 5

#### COVERAGE CRITERIA

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

- **IgE-mediated allergic asthma:** For adults and adolescents 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.

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

- 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)

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.
- 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:

<b>ADMINISTRATION EVERY 4 WEEKS (Milligrams of omalizumab)</b>				
<i>Pre-treatment Serum IgE (IU/mL)</i>	<i>Body Weight (kg)</i>			
	30-60	61-70	71-90	91-150
30-100	150	150	150	300
101-200	300	300	300	
201-300	300			
<b>ADMINISTRATION EVERY 2 WEEKS (Milligrams of omalizumab)</b>				
<i>Pre-treatment Serum IgE (IU/mL)</i>	<i>Body Weight (kg)</i>			
	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				

## PRECAUTIONS:

- Anaphylactic reactions (e.g. bronchospasm, hypotension, syncope, urticaria, angioedema) may occur with first dose or beyond one year of therapy
- 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 rarely reported
- Helminth infections may occur in patients at high risk for geohelminth infections
- Fever, arthritis, arthralgia, rash, and lymphadenopathy, similar to the signs and symptoms of serum sickness; have been reported 1 to 5 days after the first or subsequent omalizumab dose; discontinue if symptoms develop

## Billing/Coding information

### HCPCS Code:

J2357	injection, omalizumab, 5 mg
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### Associated CPT Coding:

96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
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### Associated ICD-9 Coding:

493.00	Extrinsic asthma, unspecified
493.01	Extrinsic asthma with status asthmaticus
493.02	Extrinsic asthma with (acute) exacerbation

## COST

- AWP (March 2010): 150 mg vial: \$694.58
- AWP (January 2012): 150 mg vial: \$797.10

## COMMITTEE APPROVAL:

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## GUIDELINE UPDATE INFORMATION:

March 2010	Policy creation
January 2012	Policy updated

## REFERENCES:

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