



## Clinical Edit Criteria Proposal

Drug/Drug Class: Xolair<sup>®</sup> Clinical Edit  
 Date: June 17, 2004  
 Revised: **December 23, 2009**  
 Prepared for: MO HealthNet  
 Prepared by: ACS-Heritage Information Systems, Inc.

New Criteria

Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Xolair<sup>®</sup> (Omalizumab).

**Why was this Issue Selected:**

This product is indicated in the treatment of moderate to severe **persistent** asthma in adults and adolescents with perennial allergic asthma not controlled with inhaled steroids. The product shows efficacy in reduction of exacerbations in asthma patients with IgE-mediated diseases. However, with the recommended dosage and administration of 150-375mg SQ every 2-4 weeks, the cost of the drug is a concern.

Program-specific information:	Drug	Package Size	Cost per Vial
	<ul style="list-style-type: none"> <li>Xolair<sup>®</sup> is supplied as a lyophilized sterile powder for injection.</li> </ul>	150mg/vial	\$542.00 AWP

**Setting & Population:** Adults and adolescents with perennial allergic asthma

**Type of Criteria:**

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

**Data Sources:**

<input type="checkbox"/> Only administrative databases	<input checked="" type="checkbox"/> Databases + Prescriber-supplied
--	---

## Setting & Population

- Drug class for review: Omalizumab (Xolair<sup>®</sup>)
- Age range: 12 years of age and older
- Gender: Male and female

## Approval Criteria

- 1) Omalizumab must be prescribed by a specialist (e.g., allergist, immunologist, pulmonologist) – **for initial treatment only (1<sup>st</sup> dose)**.
- 2) In order to be approved for omalizumab, a patient must meet all three of the below criteria (i.e., asthma diagnosis, prescription drug claim history indicating inadequately controlled asthma, and skin testing **or RAST or in vitro reactivity at least one perennial aeroallergen**).
- 3) Documented **inadequate or poor asthma symptom control** as defined below in the last 45 days.

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Asthma	493.0, 493.1, 493.9	N/A	360 days	
Inadequately controlled asthma	N/A	<ul style="list-style-type: none"> <li>• Inhaled corticosteroids <b>and</b></li> <li>• Short-acting beta<sub>2</sub> agonists (excessive use – defined as minimum of 3 inhalers)</li> </ul>	45 days	
		<ul style="list-style-type: none"> <li>• Short-acting beta<sub>2</sub> agonists (excessive use – defined as minimum of 3 inhalers)</li> </ul>	60 days	
		<ul style="list-style-type: none"> <li>• Inhaled corticosteroids <b>and</b></li> <li>• Short-term steroid use</li> </ul>	45 days	
		<ul style="list-style-type: none"> <li>• Inhaled corticosteroids <b>and</b></li> <li>• Emergency room visit</li> </ul>	45 days	

Evaluated Procedures		
CPT Description	CPT Codes	Date Range
Percutaneous skin testing	95024, 95028, 95004	3 months
RAST allergy testing	86003	3 months

## Denial Criteria

- Absence of approval criteria
- Age < 12 years

## References

1. USPDI, Micromedex; 2009.
2. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2009.
3. Genentech, Inc. Package Insert for Xolair® (Omalizumab). July 2008

## Appendix

<b>ICD-9 Diagnosis Code Definitions</b>	
<b>Condition</b>	<b>Code</b>
Asthma	493.0, 493.1, 493.9
<b>CPT Procedure Code Definitions</b>	
<b>Procedure</b>	<b>Code</b>
Percutaneous skin testing	95024, 95028, 95004
RAST allergy testing	86003