

# Medical Coverage Policy | Omalizumab for Allergic Asthma



**EFFECTIVE DATE:** 09/01/2004  
**POLICY LAST UPDATED:** 08/06/2013

## OVERVIEW

The policy documents requirements necessary for coverage of omalizumab therapy services for individuals with allergic asthma.

## PRIOR AUTHORIZATION

Preauthorization is required for BlueCHiP for Medicare and recommended for Commercial products.

## POLICY STATEMENT

### BlueCHiP for Medicare and Commercial products:

Omalizumab therapy is medically necessary when all of the criteria are met.

For contracts with specialty drug coverage, please refer to the member agreement for benefits and prior authorization guidelines.

## MEDICAL CRITERIA

Criteria 1 and 2 must be met for the initial therapy.  
Criteria 1 and 3 must be met for the continuation of use.

1. Omalizumab may be considered medically necessary in adults and adolescents (12 years of age and older) with allergy-induced asthma when all of the following criteria is met:
  - a. Moderate to severe persistent asthma; and
  - b. A positive skin test or in-vitro reactivity to a perennial aeroallergen; and
  - c. Symptoms that are inadequately controlled with inhaled corticosteroids at the optimal dose and/or combination agents or cannot tolerate these medications; and
  - d. A pretreatment serum IgE level is equal to or greater than 30 IU/mL; and
  - e. An FEV1 < 80% predicted; and
  - f. Symptoms are inadequately controlled despite optimal use of a long acting beta-2 agonist or leukotriene modifier/theophylline; and
  - g. Adherence/persistent with prescribed asthma treatments; and
  - h. A nonsmoker.
  
2. For the initial use of Omalizumab therapy all of the following criteria must be met :
  - a. A diagnosis of moderate or severe persistent asthma; and
  - b. And are 12 years of age or older; and
  - c. Omalizumab will be used in combination with other medications for long-term control of asthma; and
  - d. Will have a short-acting beta-agonist available for rescue therapy; and
  - e. Omalizumab will be given in a controlled health care setting with access to emergency medications if needed; and
  - f. Will be provided with an epinephrine self-injection pen in case of delayed allergic or anaphylactic reaction; and
  - g. Meet criteria for initial therapy or continuation of therapy as listed in this policy.

3. For the continuation of use of Omalizumab therapy all of the following criteria must be met:
  - a. Asthma control has improved on Omalizumab treatment; or
  - b. Documented clinical reason for lack of improvement..

**BACKGROUND**

Omalizumab (Xolair) is a recombinant DNA-derived humanized monoclonal anti-immunoglobulin E (IgE) antibody that selectively binds to human IgE. Omalizumab has been shown to decrease the incidence of asthma exacerbation in patients with allergy-induced asthma.

Allergy tests are required to identify patients who may be candidates for omalizumab therapy. Initial administration or prescription should be given by a consulting specialist with significant training and experience in the diagnosis and treatment of asthma and allergies. Food and Drug Administration (FDA) approved indications are for adults and adolescents (12 years of age and older) who have moderate-to-severe persistent asthma, a positive skin test, or in vitro reactivity to a perennial aeroallergen, and whose symptoms are inadequately controlled with inhaled corticosteroids.<sup>1</sup> Omalizumab dosing is based on body weight and pretreatment serum total IgE level. A course of treatment is given every two to four weeks indefinitely. The maximum dosage is 375 mg every two weeks or 300 mg every four weeks based on initial IgE.

Omalizumab is administered by the subcutaneous route; however, due to the potential for adverse effects, it must be given in the physician's office or facility and is not considered a self administered drug.

**COVERAGE**

**BlueCHiP for Medicare |**

**Commercial |**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for applicable durable medical equipment/ prosthesis benefits/coverage.

**CODING**

J2357	Injection, omalizumab, 5 mg
96372	

**RELATED POLICIES**

Not applicable.

**PUBLISHED**

Provider Update	Sep 2013
Provider Update	Jul 2012
Provider Update	Mar 2011
Provider Update	Apr 2010
Provider Update	Dec 2009
Policy Update	Jan 2008
Policy Update	Dec 2006
Policy Update	Oct 2005

## REFERENCES

<sup>1</sup>Xolair subcutaneous injection (package insert). South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; June 2003. <http://www.xolair.com/index.html>.

National Heart, Lung, and Blood Institute. *Expert Panel Report 2: Guidelines for the Diagnosis and Management of Asthma*. National Institutes of Health; 1997:97-4051. [http://www.getasthmahelp.org/main\\_guidelines.asp](http://www.getasthmahelp.org/main_guidelines.asp).

Physician Desk Reference; 58; 2004:1374-1376.

Rosenwasser, LJ, Nash, DB. *Incorporating Omalizumab in Asthma treatment Guidelines: Consensus Panel Recommendations*. Pharmacy & Therapeutics; June 2003; 28(6).

Self, TH, James, AW, Finch, CK. *Omalizumab (rhuMAb-E25)*. Formulary; August 2001:36.

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