

## Medical Affairs Policy & Procedure

**Title/Service:** Xolair (omalizumab)

<b>Revised</b>	11/18/11
<b>Reviewed</b>	01/23/04, 06/29/06, 02/16/07, 02/05/10
<b>Developed</b>	
<b>Policy Committee Approval</b>	11/18/11

### **Description:**

Xolair is a recombinant DNA-derived humanized monoclonal anti-immunoglobulin E (IgE) antibody, used for the treatment of allergic asthma. Xolair works by selectively binding to IgE, preventing it from attaching to mast cells and basophils, thereby limiting the release of mediators of the allergic response.

### **Indications of Coverage:**

Xolair is indicated for individuals twelve years of age and older with ALL of the following:

Moderate to severe persistent allergic asthma requiring the use of medications for a minimum of three months. Moderate to severe persistent asthma is defined as (ALL of the following must be documented):

Evidence of reversible obstructive airway obstruction **OR** positive methacholine or exercise challenge test

Symptoms (coughing, wheezing, dyspnea) that occur at least twice per week

Inadequate asthma control documented by increased use of the emergency department, urgent care, or inpatient services; impairment in functions of daily living, or excessive use of short-acting beta-agonists or oral steroids

A forced expiratory volume in one second (FEV1) less than 80% of predicted

Documentation that the individual is compliant with all recommendations for environmental controls (for example, avoiding smoke and or allergens)

Positive skin test or in vitro reactivity (for example, RAST test) to a perennial airborne allergen

Serum IgE level equal to or greater than 30 IU/ml

Symptoms that are inadequately controlled despite the regular, consistent use for a minimum of three consecutive months of the following:

At least a medium dose of inhaled corticosteroids and long-acting beta-agonist (may be combined with the corticosteroid in products such as Symbicort or Advair). If there is a contraindication to a LABA, then a leukotriene modifier ([Singulair](#) (montelukast sodium), [Accolate](#) (Zafilukast), or [Zyflo](#) (Zileuton) is acceptable.

Oral corticosteroid (Need for frequent bursts of oral corticosteroid or the inability to wean from daily corticosteroids after failure of other therapies)

Documentation of a written asthma action plan that includes instructions for (1) daily management, and (2) recognizing and handling worsening asthma, including self-adjustment of medications in response to acute symptoms or changes in peak expiratory flow (PEF) measures

A charge for administration of the medication may be allowed once per date of service.

If criteria are met, treatment is approved for six months. Subsequent treatment may be approved in one year increments with review of continued therapeutic response and **consistent** prescription medication use.

Dosage and administration: Xolair is administered subcutaneously every two or four weeks in doses from 150 to 375 mg. Due to the risk of anaphylaxis after administration, Xolair is given by healthcare professionals in most cases.

### **Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

The use of Xolair in children younger than twelve years of age may be considered on a case-by-case basis.

The use of Xolair for conditions other than moderate to severe persistent allergic asthma is considered experimental or investigative.

### **Documentation Required:**

- Office notes with comprehensive examination and history
- Pulmonary function tests
- Prescription medication use data

- Serum IgE results

### **Rationale:**

This policy is generally based on the recommendations of the National Heart, Lung, and Blood Institute's Guidelines. Several randomized, double blind, placebo-controlled multi-center trials studied the effectiveness of Xolair by evaluating the number of asthma exacerbations. The studies included patients over twelve years old with moderate to severe persistent asthma (as defined by the National Heart Lung and Blood Institute), a positive skin test, and total IgE level greater than 30 IU/ml (dosage of Xolair is determined by total IgE level measured before the start of treatment). Treatment with Xolair for serum IgE level less than 30 IU/ml was not evaluated. The number of exacerbations was reduced in individuals receiving Xolair when compared to the placebo group. Allergen-specific IGE has not been shown to provide better prediction of response to Xolair than total IGE.

Xolair has not been approved by the FDA for conditions other than asthma.

The National Asthma Education and Prevention Program Expert Panel recommended that physicians provide the individual with a written action plan on avoiding situations that would lead to an exacerbation, including recommendations for environmental control and other preventive efforts that may be necessary to avoid or reduce the impact of exacerbations.

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*Approved by the Medical Director*