

Origination Date: 5/07	Revision Date(s): 5/08
Developed By: Medical Criteria Committee	

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Description:

Xolair (omalizumab) is the first biotechnology treatment for asthma and the first approved therapy designed to target the antibody IgE, a key underlying cause of the symptoms of allergy related asthma. Xolair received FDA approval in June 2003 and has been shown to decrease the incidence of asthma exacerbations in patients with moderate to severe persistent asthma who have positive reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is administered as a monthly subcutaneous injection.

Criteria:

Xolair will be covered to plan limitations when **all** of the following criteria are met:

1. The patient is 12 years of age or older; and
2. The prescribing provider is a physician specializing in allergy or pulmonary medicine; and
3. The patient does not currently smoke cigarettes; and
4. The patient has moderate to severe asthma as evidenced by **one** of the following:
 - a. Experiences daily asthma symptoms; or
 - b. Daily use of inhaled short-acting beta₂ agonist (e.g. albuterol); or
 - c. Exacerbations ≥ 2 times per week; or
 - d. Nighttime symptoms > 1 time per week; or
 - e. FEV₁ or PEF $< 80\%$ predicted; or
 - f. Diurnal PEF variation $> 30\%$
5. The patient has a positive skin test or RAST test to a perennial aeroallergen; and
6. The patient has a history of therapeutic failure, intolerance or contraindication to specific allergy immunotherapy (i.e. allergy shots); and
7. The patient has demonstrated therapeutic failure to an inhaled or oral corticosteroid product combined with a second asthma controller such as long-acting inhaled beta₂ agonist (e.g. Serevent, Foradil or Advair), leukotriene modifier (e.g. Singulair or Accolate) or theophylline; and
8. The patient's baseline IgE serum level is ≥ 30 IU/ml.

If the above criteria is met, ODS will approve Xolair for 1 year

ODS does not cover Xolair for the following indications because it is considered experimental/investigational as the safety and effectiveness for these indications has not been established:

1. Non-allergic asthma
2. As initial therapy for allergic asthma
3. Allergic conditions without asthma
4. Seasonal or perennial allergic rhinitis
5. Food allergies

Renewal Criteria:

For continued authorization of Xolair, the following criteria must be met:

1. In the previous year, the patient has experienced at least a 25% reduction in asthma exacerbations (i.e. hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair baseline; **and**
2. If the patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair, the patient has been able to reduce their oral corticosteroid dose by 75% from their pre-Xolair baseline or to ≤ 5 mg daily; **or**

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3. The patient has been able to reduce their inhaled corticosteroid dose by at least 25% from their pre-Xolair dose.

Information to be Submitted with Pre-Authorization Request:

1. Documentation for the treating provider that establishes the patient has moderate to severe allergic asthma and includes the following:
 - a. Results of allergy skin test or RAST test showing a positive result to a perennial aeroallergen
 - b. Allergy immunotherapy history
 - c. Asthma treatment tried and failed
 - d. IgE serum level

References:

- American Lung Association Fact Sheet: Asthma in Adults. Aug 2006. Available at <http://www.lungusa.org/asthma/aduasthmfac99.html>.
- Casale TB. FDA approves omalizumab (xolair), a recombinant anti-IgE antibody, to treat moderate to severe allergic asthma. American Academy of Allergy Asthma & Immunology. June 2003. Available at <http://www.aaaai.org/members/hottopic/omalizumab/professional.stm>.
- Hayes Alert. Anti-immunoglobulin E therapy for severe allergic reaction. Winifred S. Hayes, Inc. April 2003. VI(4).
- Hayes Alert. Omalizumab for allergic asthma. Winifred S. Hayes, Inc. June 2003. VI(6).
- Humbert M, Beasley R, Ayres J, et al. Benefits of omalizumab as add-on therapy in patients with severe persistent asthma who are inadequately controlled despite best available therapy. Allergy. 2005 Mar;60(3):309-16.
- Brown R, Turk F, Dale P, et al. Cost-effectiveness of omalizumab in patients with severe persistent allergic asthma. Allergy. 2007 Feb;62(2):149-53.
- Xolair product information, Genentech/Novartis. Accessed May 2007 at <http://www.xolair.com>
- Physician Advisors