

Pharmacy Policy Bulletin

Title: Omalizumab (Xolair®)

Policy #: Rx.01.64

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly and updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

↳ Intent:

Omalizumab (Xolair®) is a monoclonal antibody indicated for the treatment of IgE-mediated allergic asthma in adults and adolescents (12 years of age and above).

The use of omalizumab (Xolair®) requires prior authorization (i.e. clinical pharmacy and/or Medical Director review).

↳ Description:

Omalizumab (Xolair®) is a monoclonal antibody that binds to naturally occurring human immunoglobulin E (IgE). It inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils. A reduction in the number of surface-bound IgE on the high-affinity IgE receptor-bearing cells limits the release of mediators of the allergic response and plays a significant role in asthma attacks. Treatment with omalizumab (Xolair®) also reduces the number of high-affinity IgE receptors on basophils in individuals with atopic asthma. Therapy with omalizumab is reserved for patients with severe asthma and allergies who are not responding adequately to high-dose inhaled steroids and long-acting beta-agonists.

↳ Policy:

Omalizumab (Xolair®) is approved when the following inclusion criteria is met:

- Documented diagnosis of moderate to severe persistent asthma in individual 12 years of age and older with **all** of the following:
 - Documented trial and failure with at least **one** inhaled corticosteroid
 - Member is managed by an Allergist and/or Pulmonologist
 - Documentation of positive skin test or in vitro reactivity (RAST) to a perennial aeroallergen

↳ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

↳ References:

Xolair. Prescribing Information. Genentech, Inc. South San Francisco, CA. 2008.

Busse W, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. J Allergy Clin Immunol 2001; 108: 184-90.

Milgrom H, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (Omalizumab). Pediatrics 2001; 108-18.

Corren J, et al. Omalizumab, a recombinant humanized anti-IgE antibody, reduces asthma-related emergency room visits and hospitalizations in patients with allergic asthma. J Allergy Clin Immunol 2003; 111(1): 87-90.


American Society of Health-System Pharmacists. Respiratory Agents, Miscellaneous. In: AHFS Drug Information. Mc Evoy GK, et al., editors. ASHP (Bethesda) MD: 2007. P. 2771-2773.

Omalizumab. MICROMEDEX® Healthcare Series, Thomson MICROMEDEX, Greenwood Village, Colorado (Vol. 135 [2/11]).

Berger W, et al. Evaluation of long-term safety of the anti-IgE antibody, omalizumab, in children with allergic asthma. Ann Allergy Asthma Immunol. 2003; 91: 182-88.

National Heart, Lung and Blood Institute and the National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. U.S. Department of Health and Human Services; 2007. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>. Accessed February 28, 2012.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Xolair	omalizumab

Cross References:

Policy Version Number: 1.00
P&T Approval Date: January 12, 2012
Policy Effective Date: April 01, 2012
Next Required Review Date: January 12, 2013

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