

Policies Repository



Policy Title Omalizumab (Xolair®)

Policy Number FS.CLIN.66

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 edits. 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. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. 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.

Policy **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 (ie, clinical pharmacy and/or Medical Director review).

Policy 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 Guideline Inclusion

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

Policy Guideline Exclusion

Omalizumab (Xolair®) is denied when the following exclusion criteria is present:

- No documented diagnosis of moderate to severe persistent asthma in individual 12

years of age and older with **all** of the following:

- o Documented trial and failure with at least **one** inhaled corticosteroid
- o Member is managed by an Allergist and/or Pulmonologist
- o Documentation of positive skin test or in vitro reactivity (RAST) to a perennial aeroallergen

Policy List of Applicable Drugs

Brand Name	Generic Name
Xolair	omalizumab

Dosing and Administration

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

Policy References

1. Xolair. Prescribing Information. Genentech, Inc. South San Francisco, CA. 4/06.
2. 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.
3. Milgrom H, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (Omalizumab). *Pediatrics* 2001; 108-18.
4. 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.
5. 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.
6. Omalizumab. MICROMEDEX® Healthcare Series, Thomson MICROMEDEX, Greenwood Village, Colorado (Vol. 135 [3/08]).
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.
7. 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>

Policy Link to Related Policies

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