

Xolair[®] PA Criteria

I. Omalizumab (Xolair[®]) should be administered only in the medical office, under the supervision of the attending physician, for the following reasons:

1. **Risk of anaphylaxis.** Xolair[®] package labeling recommends, "Patients should be observed after injection of Xolair, and medications for the treatment of severe hypersensitivity reactions including anaphylaxis should be available."
2. **Complex preparation and administration.** Package labeling includes a 7-step process for preparing product for SC administration. The product must be reconstituted and takes 15-20 minutes to dissolve. Because the solution is slightly viscous, the injection may take 5 –10 seconds to administer.

II. A 3 month approval of Xolair[®] will only be granted for patients who meet ALL of the following criteria:

1. The presence of a firm diagnosis of asthma.
2. Asthma severity classified as either moderate-persistent (class III) or severe-persistent (class IV), with FEV1 or PEF < 80% predicted, based on criteria of the National Asthma Education and Prevention Program (NAEPP)
3. Presence of significant atopy, as evidenced by
 - a. positive skin testing administered and interpreted by an Allergist, and
 - b. history of significant reactivity to environmental allergens
4. Failed immunotherapy documented.
5. Baseline serum IgE levels between 30-700 IU/ml.
6. Twelve years of age or older.
7. Patients must have poorly controlled asthma, despite being compliant* with controller(s) known to be highly effective for most asthma patients, namely...
 - a. high-dose Inhaled Corticosteroids (ICS) plus
 - b. a long-acting bronchodilator or leukotriene modifier, or
 - c. ICS plus daily or every-other-day oral corticosteroids (CS), or be suffering complications from steroids in either form (ICS or CS).

* On high-dose ICS for > 3 months.

III. FEV1 or PEF improvement from baseline will be needed for renewal.

IV. Exclusionary Criteria

1. patient weighs more than 150 kg as the risk of loss of upper airway during anaphylaxis too great to risk this medication
2. IgE level greater than 700 IU/ml as the risk of anaphylaxis may be prohibitive – not known, not yet tested.