

Origination Date: 5/07	Revision Date(s): 5/08, 3/11
Developed By: Medical Criteria Committee	

Robert Neal Mills, MD

Approved: **Robert Neal Mills, MD**

Date: 03/04/11

ODS Rx ^{1.0} <input type="checkbox"/>	ODS Rx ^{2.0} <input checked="" type="checkbox"/>	OEBB <input checked="" type="checkbox"/>	OHP <input type="checkbox"/>
NON-SPECIALTY <input type="checkbox"/>	SPECIALTY <input checked="" type="checkbox"/>		
PA <input checked="" type="checkbox"/>	QLL <input type="checkbox"/>	STEP THERAPY <input type="checkbox"/>	

PURPOSE: To ensure the appropriate and safe use of Xolair for FDA approved indications.

DESCRIPTION: Omalizumab is a recombinant DNA-derived humanized IgG1 κ monoclonal antibody that selectively binds to human IgE. Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor (Fc ϵ RI) on the surface of mast cells and basophils. Reduction in surface-bound IgE on Fc ϵ RI-bearing cells limits the degree of release of mediators of the allergic response. Treatment with omalizumab also reduces the number of Fc ϵ RI receptors on basophils in atopic patients. Xolair is not to be used as replacement therapy for traditional asthma control medications. It is intended to be used in combination with other controller medications such as inhaled corticosteroids.

INDICATIONS:

- Asthma:
 - For adults and adolescents 12 years of age and older with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
 - Omalizumab has been shown to decrease the incidence of asthma exacerbations in these patients. Safety and efficacy have not been established in other allergic conditions

PRODUCT AVAILABILITY:

Xolair (omalizumab): 150mg injection, solution reconstituted

QUANTITY LIMITS:

Xolair (omalizumab): 150mg – 6 vials per 30-day supply

GUIDELINES FOR USE:

- 1) **Is the patient greater than 12 years of age?**
 - a) **If yes, go to #2**
 - b) **If no, forward to clinical for review**
- 2) **Is a physician specializing in Allergy, Pulmonology, or Immunology currently prescribing or supervising treatment?**
 - a) **If yes, go to #3**
 - b) **If no, forward to clinical for review**
- 3) **Does the patient currently smoke cigarettes?**
 - a) **If yes, forward to clinical for review**

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- b) **If no, go to #4**
- 4) **Does the patient have a positive skin prick or RAST test to perennial aeroallergen?**
 - a) **If yes, go to #5**
 - b) **If no, forward to clinical for review**
- 5) **Does the patient have a based line IgE serum level greater than or equal to 30IU/mL?**
 - a) **If yes, go to #6**
 - b) **If no, forward to clinical for review**
- 6) **What is the patient's diagnosis?**
 - a) **If moderate to severe asthma, go to #7**
 - b) **If perennial allergic rhinitis, go to #8**
 - c) **If other, forward to clinical for review**
- 7) **Has the patient demonstrated therapeutic failure to an inhaled product combined with a long-acting beta-agonist (Serevent, Foradil, Advair), leukotriene modifier (Singulair or Accolate), or theophylline resulting in hospitalization or use of oral or parenteral corticosteroids to control symptoms?**
 - a) **If yes, go to #11**
 - b) **If no, forward to clinical for review**
- 8) **Has the patient tried and failed at least one drug from two of the following groups of drugs at the same time during one allergy season?**
 - i) **Nonsedating antihistamine (Allegra, Claritin, Clarinex, Zyrtec, or their combinations with pseudoephedrine)**
 - ii) **Nasal corticosteroid (Beconase AQ or Flonase)**
 - iii) **Leukotriene modifier (Singulair or Accolate)**
 - a) **If yes, go to #9**
 - b) **If no, forward to clinical for review**
- 9) **Is the patient receiving or has the patient previously received immunotherapy?**
 - a) **If yes or immunotherapy is unavailable, go to #10**
 - b) **If no, forward to clinical for review**
- 10) **If the patient has allergies to animals, have the animals been removed from the home environment?**
 - a) **If yes, go to #11**
 - b) **If no, forward to clinical for review**
- 11) **Approve for one year per the above quantity limitations**