Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

XOLAIR® (omalizumab)

GPI CODING:

44603060002120

DESCRIPTION:

Xolair is a recombinant DNA-derived humanized monoclonal antibody that selectively binds to human immunoglobulin E (IgE). The product inhibits the binding of IgE to a high-affinity IgE receptor on the surface of mast cells and basophils. Reduction in the surface bound IgE limits the degree or release of mediators of the allergic response, and thus may decrease the frequency of asthma exacerbations.
Xolair is indicated for adults and adolescents (12 years of age and above) 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.

APPROVAL DURATION:

Approval duration: 1 year

CRITERIA FOR XOLAIR

I. Patient has a diagnosis of moderate or severe persistent asthma **AND**
II. Patient is 12 years of age or older **AND**
III. Xolair will be used in combination with other medications for long-term control of asthma **AND**
IV. Patient will have a short-acting beta-agonist available for rescue therapy **AND**
V. Xolair will be given in a controlled health care setting with access to emergency medications if needed **AND**
VI. Patient will be provided with an epinephrine self-injection pen in case of delayed allergic or anaphylactic reaction **AND**
VII. Patient must meet criteria for initial therapy or continuation of therapy in II or III below

Criteria for initial Xolair therapy:
I. Patient has a positive skin test or in vitro reactivity to a perennial aeroallergen **AND**
II. Patient has a pre-treatment IgE level is equal to or greater than 30 IU/ml **AND**
III. Asthma symptoms are inadequately controlled despite use of inhaled corticosteroid at the optimal dose **AND**
IV. Asthma symptoms are inadequately controlled despite optimal use of a long acting beta-2 agonist or leukotriene modifier/theophylline **AND**
V. Patient has been adherence/persistent with prescribed asthma treatments

Authorization for continued use shall be reviewed at least every 12 months to confirm the following: patient's asthma control has improved on Xolair treatment or there is a documented clinical reason for lack of improvement.