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Objective:

I. To provide THA providers with standardized criteria under which Xolair is considered appropriate.

II. To ensure THA members have access to the appropriate medications that treat their condition as well as meeting standard guidelines.

Definition:

Xolair (Omalizumab) is a monoclonal antibody that binds selectively to IgE preventing cells from generating the release of allergic response mediators. It has been shown to be an adjunctive therapy for patients whose asthma is inadequately controlled despite regular use of inhaled corticosteroids. Xolair should never be used as a monotherapy. It is indicated for adults and adolescents with moderate to severe persistent asthma which has not responded to recommended therapies.

Policy:

I. To be initially eligible for treatment with Xolair, the member must meet all of the following:

A. Be 12 years of age or above

B. Be diagnosed with moderate to severe persistent asthma – All symptoms must be present.
   1. Symptoms at least every day that limit activity.
   2. Night-time awakenings due to asthma at least one night per week.
   3. Use of short-acting bronchodilators at least one time per day.
   4. Results of recent pulmonary function tests indicating FEV of 80% or less of predicted and FEV/FVC < 80%.

C. Have results showing a positive skin test or in vitro reactivity to at least one perennial aeroallergen (pin-prick or RAST testing).

D. Have an IgE level greater than 30 IU/ml

E. Symptoms must be inadequately controlled on inhaled corticosteroids and/or oral leukotriene inhibitors (Accolate or Singulair). Recommendations are that if the member is on a medium dose of ICS, it should be in combination with long-acting inhaled B2 agonist or leukotriene modifier and be administered for a period of at least 3 months duration. Documentation of chronic administration of systemic corticosteroids or continued use of a high-dose ICS without adequate control of symptoms (requiring daily rescue medication) will meet the criteria.

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F. Evaluation to determine the necessity for Xolair and prescription of the medication should be by a consulting specialist (pulmonologist or allergist) with training in diagnosing and treating asthma.

G. The medication must be administered in the physician's office by a health care professional. Arrangements should be made to observe the member for a time after administration. Anaphylaxis is a potential reaction, even after the first dose.

   a. Dosing is weight and IgE dependent and must be administered according to the guidelines in the Xolair package insert.
   b. Dose will need to be adjusted periodically for significant weight changes.

H. Member must be a non-smoker

II. If the member meets the above criteria, they are to be approved for up to 6 months of treatment.

III. After 6 months of treatment, eligibility for continuation of therapy will be based on:

A. No adverse side effects from the medication.

B. Improved symptom control and decreased exacerbations compared to pretreatment period.

C. Reduction of oral steroid dose if previously required.

D. If the member meets the above criteria, they may be approved for an additional 6 months of therapy.

IV. Continued therapy after 12 months

A. Continued symptom control and decreased exacerbations.

B. Decrease in the use of rescue medications based on a biannual reevaluation by the physician.

V. Xolair will not be covered when:

A. Above outlined conditions are not met.

B. Treating acute asthma exacerbations, acute bronchospasm, or status asthmaticus.

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C. Treating allergic rhinitis.

VI. Administration of Xolair (omalizumab):
CPT: 95117 – administration of immunotherapy
HCPCS: J2357 – injection omalizumab, 5 mg

References:
Xolair Prescribing Fact Sheet
Blue Cross Blue Shield Xolair Medical Policy
Providence Xolair Medical Policy
Drug Packaging information

Formulated:	April 2008
Reviewed:	February 2013 July 2015 August 2017
Revised	June 2011