



Guidelines for Coverage:

Omalizumab (Xolair®)

Background:

Omalizumab is a recombinant DNA- derived humanized monoclonal antibody that is specific for IgE. It is approved for use in adolescents and adults 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 binds to free IgE, thereby preventing it from binding to mast cells, basophils, and other cells that contain inflammatory mediators.

Administration:

Xolair® is administered via subcutaneous injection. The dose based on the patient's weight and pretreatment serum IgE level. Approved doses range from 150mg to 375mg administered every two to four weeks. Due to the potential for bronchoconstriction/allergic-type reaction reaction, the first several doses should be administered in a setting that allows for monitoring by medical personnel after administration.

The most widely reported side effects of omalizumab are injection site reactions. Other reported adverse reactions include upper respiratory and other infections, headache, and sinusitis. Anaphylaxis occurred in less than 0.1% of patients treated with omalizumab. A higher incidence of malignancies (0.5% vs. 0.2%) occurred in omalizumab treated patients than in placebo treated patients.

Criteria for approval:

1. Xolair® therapy must be directed by a certified pulmonologist or allergist.
2. Candidates for Xolair® must have moderate persistent to severe persistent asthma based on the current Guidelines for the Diagnosis and Management of Asthma of the National Heart, Lung, and Blood Institute; **AND**
3. The member must be at least 12 years old; **AND**
4. The member must have a serum IgE level greater than or equal to 30 IU/ml; **AND**
5. The member has been shown to have specific perennial allergen sensitivity as documented by a positive skin test or blood test for IgE; **AND**

6. The member has reversible disease as defined by a greater than 12% improvement in FEV₁ with at least a 200ml increase or at least 20% or greater improvement in PEF; **AND**
7. The member's asthma is inadequately controlled despite medium doses of inhaled corticosteroids in combination with a trial of a long-acting beta-agonist or leukotriene modifier; **AND**
8. Systemic corticosteroids or high dose inhaled corticosteroids are required to maintain adequate asthma control; **AND**
9. The member is enrolled in and is compliant with the SummaCare asthma disease management program.
10. Xolair therapy should be administered in an office setting where the patient can be monitored for an adverse event following administration.

Special Instructions:

Prescriptions for Xolair® will be filled by Walgreens Specialty, the contracted SummaCare provider. Doses will be shipped directly to the office of the prescribing physician. Walgreens Specialty will coordinate logistics with the physician office. When administered in a physician's office setting, Xolair® is covered under the SummaCare medical benefit.

Approved: SummaCare Pharmacy & Therapeutics Committee November 6, 2003

Reviewed and Approved: January 10, 2008

Medical Director

Pharmacy Director

References:

National Heart, Lung, and Blood Institute. *Guidelines for the Diagnosis and Management of Asthma*. July 1997.

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Buhl R, Soler M, Townley R, et al. Omalizumab Provides Long-term Control in Patients with Moderate-to-severe Allergic Asthma. *Eur Respir J* 2002; 20: 73-78.