Subject: Omalizumab (Xolair®)*

Effective Date: October 28, 2008

Department(s): Utilization Management

Policy: Xolair is reimbursable under Plans administered by QualCare, Inc. when used according to the criteria in this policy.

Objective: To assure proper and consistent reimbursement and to delineate circumstances under which a specific drug is covered.

Procedure:

A. Individuals for whom Xolair® is reimbursable must be at least 12 years of age, have poorly controlled moderate-to-severe asthma (see below) and meet all of the following criteria:

1. There must be documentation of atopy either with a positive skin test or in vitro reactivity (by RAST or comparable testing) to at least one perennial airborne allergen OR a clearly documented history of asthma in response to an inhaled allergen

2. The pre-treatment IgE level must be at least 30 IU/mL

3. Symptoms must be poorly controlled with inhaled corticosteroids AND long-acting beta-agonists (e.g., salmeterol [Serevent®, Advair®]) or leukotriene inhibitors (e.g., montlukast [Singulair®]) for at least 3 months

4. Symptoms of wheezing, cough, or dyspnea occur daily and interfere with activities of daily living and/or sleep

B. For the purposes of this policy, poor asthma control is characterized by at least one of the following:
1. Use of a short-acting inhaled beta2-agonist (“rescue” inhaler) more than 2 days a week.

2. Variation of peak expiratory flow rate of more than 30% over the course of a day

3. Peak expiratory flow rate less than 80% of highest recorded for the given individual

4. Forced expiratory flow rate in 1 second (FEV1) less than 60% of predicted

5. At least three events in 12 months, from the following list:
   a. Emergency room or urgent care center visit
   b. Inpatient hospital admission for asthma
   c. Requirement of systemic (oral or injectable) steroids for control

6. In a patient taking Xolair®, worsening of asthma when it is discontinued.

C. Initial authorization of Xolair® will be for 6 months. To continue Xolair® beyond the first six months, there must be documentation of at least one of the following:

1. Decreased use of “rescue” inhaler

2. Decreased frequency of exacerbations

3. Improvement in FEV1

4. Improvement in at least one of the following symptoms:
   a. Sleep disturbance
   b. Shortness of breath
   c. Wheezing
   d. Chest tightness
   e. Frequency of asthma attacks
   f. Cough
   g. Fatigue
D. Repeated measurement of IgE in individuals taking Xolair® will not be reimbursed.

E. Xolair® is not reimbursable as initial therapy for asthma, non-allergic asthma, or allergy that is not accompanied by asthma.

References


Hendelese L, Sorkness CA. Anti-immunoglobulin E therapy with omalizumab for asthma. Ann Pharmacother 2007;41(9):1397-1410 (Sep)

*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.