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: Xolair®(omalizumab) (HCPCS code J2357)is reimbursable for the indications noted in sections I and II below when the specific medical necessity criteria are met.

I. Asthma- the individual is ≥ 12 years of age, has poorly controlled moderate-to-severe asthma (see below) and meets all of the following criteria:

A. 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.

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

C. 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.
D. Omalizumab will be add-on therapy to the current medical therapy.
E. Symptoms of wheezing, cough, or dyspnea occur daily and interfere with activities of daily living and/or sleep.
F. 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.
G. 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

H. Repeated measurement of IgE in individuals taking Xolair® will not be reimbursed.
I. Xolair® is not reimbursable as initial therapy for asthma, non-allergic asthma, or allergy that is not accompanied by asthma.

II. Chronic idiopathic urticaria (CIU) -when ALL of the following criteria are met:

A. Age 12 years or older.
B. Symptoms for at least 6 weeks.
C. Failure, contraindication, or intolerance to hydroxyzine or at least ONE other H1-antihistamine(ie doxepin)
D. Failure, contraindication, or intolerance to at least one other class of treatment: H2 antagonist (e.g., famotidine, ranitidine); leukotriene receptor antagonist (e.g., montelukast).

Note-Initial authorization of Xolair® for use in CIU will be for 6 months. Subsequent authorizations of 6 months each require documentation of continued beneficial response, continued concomitant use of an H-1 antihistamine and, where clinically appropriate, an attempt at dose reduction or discontinuation has been made.

References

Kaplan A, Ferrer M, Bernstein JA, Antonova E, et al. Timing and duration of omalizumab response in patients with chronic idiopathic/spontaneous urticaria. J Allergy Clin Immunol. 2016;137(2):474-81(Feb)

Horak F, Doberer D, Eber E, Horak E et al. Diagnosis and management of asthma - Statement on the 2015 GINA Guidelines. Wien Klin Wochenschr. 2016;128(15-16):541-54(Aug)

Saini SS, Bindslev-Jensen, Maurer M, Grob JJ et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study. J Invest Dermatol. 2015;135(1):67-75(Jan)

Labrador-Horrillo M, Ferrer M. Profile of omalizumab in the treatment of chronic spontaneous urticaria. Drug Des Devel Ther. 2015;9:4909-4915(Aug)

Bernstein JA, Lang DM, Khan DA, et al Joint Task Force on Practice Parameters. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol 2014; 133 (5): 1270-7(May)

Licari A, Marseglia A, Caimmi S, Castagnoli R, Foiadelli T, Barberi S, Marseglia GL. Omalizumab in children. Paediatr Drugs. 2014;16(6):491-502(Dec)

Maurer M, Rosen K, Hsieh HJ et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. N Engl J Med 2013; 368: 924-35.

Kaplan A, Ledford D, Ashby M et al. Omalizumab in patients with symptomatic chronic idiopathic/spontaneous urticaria despite standard combination therapy. J Allergy Clin Immunol 2013; 132: 101-9.

Busse WW, Morgan WJ, Gergen PJ, et al. Randomized trial of omalizumab (anti-IgE) for asthma in inner-city children. N Engl J Med. 2011;364(11):1005-1015

Heil PM, Maurer D, Klein B, et al. Omalizumab therapy in atopic dermatitis: Depletion of IgE does not improve the clinical course - a randomized, placebo-controlled and double blind pilot study. J Dtsch Dermatol Ges. 2010;8(12):990-998.

NICE technology appraisal guidance 201: Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 to 11 years. October 2010. Accessed online 02/10/11 at www.nice.org.uk/guidance/TA201.

Prenner BM. Asthma 2008: Targeting Immunglobulin E To Achieve Disease Control. *J Asthma* 2008;45(6):429-436 (Aug)

Sulliv SD, Turk F. An evaluation of the cost-effectiveness of omalizumab for the treatment of severe allergic asthma. *Allergy* 2008;63(6):670-684 (Jun)

Barnes PJ. Anti-IgE therapy. *UptoDate* version 16.2. May 9, 2008. Available at http://www.uptodate. com/online/content/topic.do?topicKey=asthma/18811&view=print. Accessed 09/18/08

Krouse JH, Krouse HJ. Asthma: Guidelines-Based Control and Management. *Otolaryngol Clin N Am* 2008;41(2):397-409 (Apr)

Wu AC, Paltiel AD, Kuntz KM, *et al*. Cost-effectiveness of omalizumab in adults with severe asthma: Results from the Asthma Policy Model. *J Allergy Clin Immunol* 2007;120(5):1146-1152 (Nov)

Cox L, Platts-Mills TA, Finegold I *et al.* American Academy of Allergy, Asthma & Immunology/ American College of Allergy, asthma and Immunology Joint Task Force Report on omalizumab-associated anaphylaxis. *J Allergy Clin Immunol* 2007;120(6):1373-1377 (Dec)

Kuhn R. Immunoglobulin E blockade in the treatment of asthma. *Pharmacotherapy* 2007;27(10):1412-1424 (Oct)

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

Waglie-Steffen AL, Kavanaugh AF, Wasserman SI. Biologic Therapies for the Treatment of Asthma. *Clin Chest Med* 2006;27(1):133-147 (Mar)

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