Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 18, 2012 June 23, 2014, November 23, 2015, December 29, 2015, July 25, 2016, January 11, 2017, March 29, 2017 , November 27, 2018

XOLAIR® (omalizumab)

LENGTH OF AUTHORIZATION:

Allergic asthma: One year

Initial authorization for chronic urticaria: 12 weeks (to assess ongoing need/response to therapy)

Clinical Notes:

Xolair is indicated for adults and children (ages ≥6 years) with moderate-to-severe persistent allergic asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.

Xolair is also indicated for the treatment of chronic idiopathic urticaria in adults and adolescents (ages≥12 years) that is symptomatic despite H_1 antihistamine treatment.

Specific Review Criteria for Allergic Asthma (all of the following must be met):

1. Verified diagnosis of asthma (progress notes or diagnosis codes) **AND**
2. Age ≥ 6 years old **AND**
3. Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen **AND**
4. Patient must have a serum immunoglobulin E (IgE) level greater than or equal to 30 IU/mL **AND**
5. Patient has ongoing symptoms of asthma with a minimum three-month trial of an inhaled corticosteroid plus a Long Acting Beta Agonist (LABA) combination therapy.

Specific Review Criteria for Chronic Idiopathic Urticaria (all of the following must be met):

1. Age ≥ 12 years old **AND**
2. Patient has urticaria persisting for more than 6 weeks duration and the underlying cause of the patient's condition has been examined and has been found to not be any other allergic condition(s) **AND**
3. Trial and failure of a first or second generation antihistamine alone or in combination with a H_2 antagonist **AND**
4. Trial and failure of with a leukotriene receptor antagonist in combination with a first or second generation antihistamine.

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Continuation of Therapy for Asthma:

1. Initial approval criteria for Xolair therapy was met at the time of initiation of therapy **AND**

2. Treatment with Xolair has resulted in clinical improvement as documented by
    - One or more of the following:
        a. Decreased utilization of rescue medications; **or**
        b. Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **or**
        c. Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening.

3. Continued use of inhaled corticosteroid plus a LABA combination while on Xolair therapy for asthma is documented **AND**

4. Patients should periodically be reassessed for the need to continue therapy based on the disease severity and/or the level of asthma control.

Continuation of Therapy for Chronic Idiopathic Urticaria:

Treatment with Xolair has resulted in documented clinical improvement.

Dosing and Administration:

Allergic Asthma: 75 mg to 375 mg subcutaneously every two or four weeks. Dose and frequency are determined by serum total IgE level (IU/mL) measured before the start of treatment and body weight.

Chronic Idiopathic Urticaria: 150 mg or 300 mg subcutaneously every four weeks. Dosing is not dependent on serum IgE level or body weight.