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 H₁ antihistamine treatment.

General Documentation Required:

1. A copy of one of the specialty pharmacy network enrollment forms completed by the prescriber. Verify form is originated from one of the approved specialty pharmacy networks (name should be on enrollment form):
   http://www.xolair.com/ciu/hcp/xolair-resources.html
2. A copy of the Xolair prescription.

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 H₂ antagonist AND
4. Trial and failure of with a leukotriene receptor antagonist in combination with a first or second generation antihistamine.
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 be periodically 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.

References:
Xolair [package insert], South San Francisco, CA; Genentech, Inc.; July 2016