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; September 8, 2021; April 22, 2022, January 24, 2024

XOLAIR® (omalizumab)

LENGTH OF AUTHORIZATION:
Allergic asthma and nasal polyps: One year
Chronic idiopathic urticaria: Up to One year

INITIAL REVIEW CRITERIA:

Allergic Asthma

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.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

1. Verified diagnosis of chronic rhinosinusitis with nasal polyps (progress notes or diagnosis codes) **AND**
2. Age ≥ 18 years old **AND**
3. Xolair is being prescribed as add-on maintenance treatment of nasal polyps and patient will continue nasal corticosteroid **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 nasal polyps with a minimum three-month trial of nasal corticosteroids.

Chronic Spontaneous Urticaria (CSU)

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.

CONTINUATION OF THERAPY:

Allergic 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.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

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 improvement in nasal polyps and nasal congestion symptoms **AND**
3. Continued use of nasal corticosteroid while on Xolair therapy for nasal polyps 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 symptom control.

Chronic Spontaneous Urticaria (CSU)

1. Treatment with Xolair has resulted in documented clinical improvement.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as:
  - 75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL solution in a single-dose prefilled syringe
  - 75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL solution in a single-dose prefilled autoinjector
  - 150 mg lyophilized powder in a single-dose vial for reconstitution