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, May 8, 2024, August 19, 2024

XOLAIR® (omalizumab)

LENGTH OF AUTHORIZATION:

Allergic Asthma, Chronic Rhinosinusitis with Nasal Polyp, and IgE-Mediated Food Allergy: One year
Chronic Spontaneous Urticaria: Up to One year

INITIAL REVIEW CRITERIA:

- Xolair will not be used in combination with other biologics (e.g. Dupixent, Remicade, Enbrel, Humira, etc.).

Asthma

- Patient must be ≥ 6 years old; **AND**
- Must have a diagnosis of moderate to severe persistent asthma; **AND**
- Patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen **AND**
- Prescribed by or in consultation with an allergist, pulmonologist, or immunologist; **AND**
- Patient must have a serum immunoglobulin E (IgE) level ≥ 30 IU/mL (documentation required); **AND**
- Patient has ongoing symptoms of asthma with a minimum three-month trial of an inhaled corticosteroid plus a long-acting beta 2 agonist (LABA) combination therapy.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Patient must be ≥ 18 years old; **AND**
- Must have a diagnosis of chronic rhinosinusitis with nasal polyps (progress notes or diagnosis codes); **AND**
- Patient is inadequately controlled with first line therapy (inflammation of the paranasal sinuses lasting more than 12 weeks); **AND**
- Xolair is add on therapy to first line treatment: intranasal or oral corticosteroids, nasal saline irrigations, and 3-4 week courses of antibiotics (submission of current therapy required); **AND**
- Patient must have a serum IgE level ≥ 30 IU/mL.

Chronic Spontaneous Urticaria (CSU)

- Patient must be ≥ 12 years old; **AND**
- 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**
- Trial and failure of a first or second generation antihistamine alone or in combination with a H_2 antagonist; **AND**
- Trial and failure of with a leukotriene receptor antagonist in combination with a first or second generation antihistamine.

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IgE-Mediated Food Allergy

- Patient must be ≥ 1 years old; **AND**
- Xolair is being prescribed for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods; **AND**
- Xolair is being prescribed in conjunction with food allergen avoidance; **AND**
- Xolair is NOT being prescribed for the emergency treatment of allergic reactions, including anaphylaxis.

CONTINUATION OF THERAPY:

- Initial approval criteria for therapy has been met at the time of initiation of therapy.
- Xolair will not be used in combination with other biologics (e.g. Dupixent, Remicade, Enbrel, Humira, etc.).
- Dosing is appropriate as per labeling or is supported by compendia.

Asthma

- Treatment with Xolair has resulted in clinical improvement as documented in progress notes by:
    - One or more of the following:
        - Decreased utilization of rescue medications; **OR**
        - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
        - 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.
- Continued use of inhaled corticosteroid plus a LABA combination while on Xolair therapy for asthma is documented **AND**
- 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)

- Treatment with Xolair has resulted in clinical improvement as documented in the progress notes.

Chronic Spontaneous Urticaria (CSU)

- Treatment with Xolair has resulted in clinical improvement as documented in the progress notes.

IgE-Mediated Food Allergy

- Treatment with Xolair has resulted in clinical improvement as documented in the progress notes; **AND**
- Continued use in conjunction with food allergen avoidance.

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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