SmartHealth

Ascension

Omalizumab

(Xolair®) J2357

Covered with prior authorization

Omalizumab (Xolair®) may be authorized when the following criteria are met:

- Individual is ≥ 6 years of age; **AND**
- Adult individual with moderate to severe allergic/eosinophilic asthma that is not controlled on at least medium-dose inhaled corticosteroids (ICS) **and** at least one controller drug **and/or** oral corticosteroids for at least 3 months; **AND**
- Serum total IgE:
    - 30-700 IU/mL (adolescents/adults 12+ years of age); **OR**
    - 30-1300 IU/mL (pediatrics 6-12 years of age); **AND**
- FEV1 </= 80%; **AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
- Dose is 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and by body weight (kg).

Exclusion criteria:

- Individuals less than 6 years of age;
- Individuals who smoke;
- Individuals who use chronic oral steroids;
- Individuals for whom a dose cannot be recommended based on age, weight, and pretreatment IgE (refer to tables above);
- Severe hypersensitivity reaction to omalizumab or any component of the formulation;
- Individuals with acute bronchospasm or status asthmaticus;
- Individuals with other allergic conditions or other forms of urticaria different from FDA approved indications above;
- Will not be used in combination with another antiasthmatic monoclonal antibody (for example, Cinqair, Nucala, Fasenra);
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease.Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

Xolair® is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment

Not indicated for acute bronchospasm or status asthmaticus

References:

Ascension. (2022, January). *Medical Specialty Respiratory Drug Review for SmartHealth: SBAR*. Ascension TAG INITIATIVES - PSWP.

Ascension. (2022, January 21). *Omalizumab Criteria for Use*. Ascension TAG INITIATIVES - PSWP.

Xolair® (omalizumab) label. (2021, april). Accessdata.fda.gov. Retrieved April 23, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/103976s5238lbl.pdf

Xolair® (omalizumab) [prescribing information] Genentech Inc.; 07/2021.

Hom S, Pisano M. Reslizumab (Cinqair): an interleukin-5 antagonist for severe asthma of the eosinophilic phenotype. P T. 2017;42(9):564-568.

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Medical Specialty Respiratory Drug Review for SmartHealth SBAR developed by Ambulatory Care Expert REview Panel
January 2022	Approved by Ambulatory Care Steering Committee
February 2022	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.