

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Xolair (omalizumab)
BILLING CODE	J2357 (1 unit = 5 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT – 375 mg or 75 units
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Xolair (omalizumab) is a **preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### CHRONIC IDIOPATHIC URTICARIA (CIU)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a dermatologist or allergist; AND
3. Member has documented weekly urticaria activity score (UAS7) of  $\geq 16$ , and a weekly itch severity score of  $\geq 8$  for the 7 days; AND
4. Member has had a 3 to 10-day trial of oral corticosteroids (prednisone or prednisolone, up to 1 mg per kg per day); AND
5. Member has tried and failed hydroxyzine or doxepin for at least 14 days; AND
6. Member has tried and failed a second generation antihistamine at the maximal FDA-approved dosage for at least 14 days; AND
7. Member has tried and failed **one** of the following:
  - a) Two second generation antihistamines given at the same time;
  - b) A second generation antihistamine and a H2 antagonist given at the same time;
  - c) A second generation antihistamine and a leukotriene receptor antagonist;
  - d) The member tried and failed a second generation antihistamine and a first generation antihistamine given at the same time.
8. **Dosage allowed:** 150 or 300 mg by subcutaneous injection every 4 weeks.

***If member meets all the requirements listed above, the medication will be approved for 16 weeks.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided with documented weekly UAS7 improvement.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

## MODERATE TO SEVERE PERSISTENT ASTHMA

For **initial** authorization:

1. Member must be 6 years of age or older with moderate to severe persistent allergic asthma; AND
2. Medication must be prescribed by a pulmonologist, immunologist or allergist for the diagnosis of asthma; AND
3. Member has Forced Expiratory Volume in 1 second (FEV1) less than 80% predicted, or detailed assessment of signs and symptoms of moderate to severe persistent asthma from provider with detailed description of why FEV1 was unable to be obtained with; AND
4. Medication is not being used as monotherapy for asthma; AND
5. Member has a baseline plasma immunoglobulin E (IgE) level above 30 IU/mL; AND
6. Member's asthma has been inadequately controlled after 3 month of conventional treatment including **one** of the following:
  - a) Medium to high doses of inhaled corticosteroids and long acting beta 2-agonists;
  - b) High dose inhaled corticosteroid and a Leukotriene Receptor Antagonists; AND
7. Member has allergy testing performed, as indicated by:
  - a) Positive skin testing for perennial aeroallergen; AND/OR
  - b) Reactivity to at least one aeroallergen documented by elevated serum IgE level.
8. **Dosage allowed:** 75 to 375 mg by subcutaneous injection every 2 or 4 weeks.

***If member meets all the requirements listed above, the medication will be approved for 16 weeks.***

For **reauthorization**:

1. Medication is not being used as monotherapy for asthma; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:
  - a) Decreased frequency of emergency department visits; OR
  - b) Decreased frequency of hospitalizations due to asthma symptoms; OR
  - c) Increase in percent predicted FEV1 from pretreatment baseline; OR
  - d) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
  - e) Decreased utilization of rescue medications.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.***

**CareSource considers Xolair (omalizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:**

- Allergic broncho-pulmonary aspergillosis
- Allergic conditions without asthma
- Atopic dermatitis
- Allergic rhinitis
- Bullous pemphigoid
- Cholinergic urticaria and urticaria of other known causes
- Eosinophilic esophagitis
- Eosinophilic gastroenteritis
- Eosinophilic pneumonia
- Food allergy (e.g. peanut allergy)

- Initial therapy for allergic asthma
- Insulin allergy
- Latex allergy
- Nasal polyposis
- Non-allergic (non-atopic) asthma
- Subcutaneous immunotherapy, adjunct
- Vibratory angioedema

DATE	ACTION/DESCRIPTION
05/18/2017	New policy for Xolair created. For CIU urticaria activity score, trial of oral corticosteroids and trial length added.

References:

1. Xolair [package insert]. South San Francisco, CA: GenentechUSA, Inc; 2016. Accessed March 2, 2017.
2. Xolair. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed March 2, 2017.
3. Buhl R. Omalizumab (Xolair) improves quality of life in adult patients with allergic asthma: A review. *Respir Med.* 2003;97(2):123-129.
4. Finn A, Gross G, van Bavel J, et al. Omalizumab improves asthma-related quality of life in patients with severe allergic asthma. *J Allergy Clin Immunol.* 2003;111(2):278-284.
5. Bang LM, Plosker GL. Omalizumab: A review of its use in the management of allergic asthma. *Treat Respir Med.* 2004;3(3):183-199.
6. Food and Drug Administration (FDA) Center for Drug Evaluation and Research. Transcript for the November 18, 2009 Meeting of the Pulmonary-Allergy Drugs Advisory Committee. Available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Pulmonary-AllergyDrugsAdvisoryCommittee/UCM198005.pdf.%20>. Accessed March 2, 2017.
7. Xolair (Omalizumab) for Subcutaneous Use. Prescribing Information. Genentech, Inc. March 2014. Available at <http://www.gene.com/gene/products/information/pdf/xolair-prescribing.pdf>. Accessed May 19, 2014.
8. National Heart, Lung, and Blood Institute. National Asthma Education and Prevention Program: Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. 2008. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>. Accessed March 23, 2011.

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