PHARMACY POLICY STATEMENT **Indiana 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 **NOT** MEDICALLY NECESSARY	Click Here

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 ≥ 16, and a weekly itch severity score of ≥ 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: GenetechUSA, 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/Pulmona ry-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. Accesses 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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