# PHARMACY POLICY STATEMENT

## Ohio Medicaid

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>Xolair (omalizumab)</th>
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</thead>
<tbody>
<tr>
<td>BILLING CODE</td>
<td>J2357 (1 unit = 5 mg)</td>
</tr>
<tr>
<td>BENEFIT TYPE</td>
<td>Medical</td>
</tr>
<tr>
<td>SITE OF SERVICE ALLOWED</td>
<td>Office/Outpatient Hospital</td>
</tr>
<tr>
<td>COVERAGE REQUIREMENTS</td>
<td>Prior Authorization Required (Preferred Product)</td>
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<tr>
<td></td>
<td>QUANTITY LIMIT — 375 mg or 75 units</td>
</tr>
<tr>
<td>LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY</td>
<td>Click Here</td>
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</tbody>
</table>

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

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>05/18/2017</td>
<td>New policy for Xolair created. For C1U urticaria activity score, trial of oral corticosteroids and trial length added.</td>
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References:

Effective date: 05/18/2017
Revised date: 05/18/2017