### Overview

Asthma: Omalizumab is an IgG monoclonal antibody (recombinant DNA derived) which inhibits IgE binding to the high-affinity IgE receptor on mast cells and basophils. By decreasing bound IgE, the activation and release of mediators in the allergic response (early and late phase) is limited. Serum free IgE levels and the number of high-affinity IgE receptors are decreased.

Chronic idiopathic urticaria: Omalizumab binds to IgE and lowers free IgE levels. Subsequently, IgE receptors (FcεRI) on cells down-regulate. Omalizumab is not indicated for acute asthma exacerbations, acute bronchospasms or status asthmaticus.

### Coverage Guidelines

Approval of Xolair will be granted if the member meets all following criteria and documentation has been submitted:

**Asthma**

1. Authorization may be granted for members who are currently receiving treatment with Xolair for moderate to severe allergic-related asthma excluding when the product is obtained as samples or via manufacturer’s patient assistance program
   
   **OR**

2. Member is diagnosed with moderate to severe allergy-related asthma
3. Member is ≥ 6 years of age
4. Prescriber is an asthma specialist (i.e., allergist, immunologist, pulmonologist)
5. Member remains symptomatic despite adherence to one of the following:
   - combination inhaler containing an inhaled corticosteroid and a long-acting β-agonist

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**Xolair (omalizumab)**

**Effective 01/01/2020**

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
<th>Benefit</th>
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</thead>
<tbody>
<tr>
<td>MassHealth</td>
<td>☒ Prior Authorization</td>
<td>☒ Pharmacy Benefit</td>
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<tr>
<td>Commercial/Exchange</td>
<td>☐ Quantity Limit</td>
<td>☒ Medical Benefit (NLX)</td>
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</tbody>
</table>

**Specialty Limitations**

This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

<table>
<thead>
<tr>
<th>Contact Information</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
<th>Medical Specialty Medications (NLX)</th>
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<tbody>
<tr>
<td></td>
<td>All Plans</td>
<td>Phone: 866-814-5506</td>
<td>Fax: 866-249-6155</td>
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<tr>
<td></td>
<td>MassHealth</td>
<td>Phone: 877-433-7643</td>
<td>Fax: 866-255-7569</td>
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<tr>
<td></td>
<td>Commercial</td>
<td>Phone: 800-294-5979</td>
<td>Fax: 888-836-0730</td>
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<td></td>
<td>Exchange</td>
<td>Phone: 855-582-2022</td>
<td>Fax: 855-245-2134</td>
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<td>Exceptions</td>
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• combination of an inhaled corticosteroid and a long-acting β-agonist inhaler as separate inhalers
• chronic oral corticosteroids

6. Member’s baseline serum IgE is between 30 IU/mL to 700 IU/mL
7. Member has evidence of specific allergic sensitivity (i.e., positive skin test or radioallergosorbent test [RAST] for IgE)

**Chronic Idiopathic Urticaria (CIU)**

1. Authorization may be granted for members who are currently receiving treatment with Xolair for CIU excluding when the product is obtained as samples or via manufacturer’s patient assistance program
   OR
2. Member is ≥ 12 years of age
3. Prescriber is an allergist/immunologist or dermatologist, or consultation notes from an allergist/immunologist or dermatologist regarding the diagnosis and treatment recommendations are submitted
4. Member has had an inadequate response, adverse reaction or a contraindication to all the following therapy combinations:
   • Treatment with at least two H1 antihistamines
   • Treatment with one H1 antihistamine taken in combination with a leukotriene antagonist
   • Treatment with one H1 antihistamine taken in combination with an H2 antihistamine

**Continuation of Therapy**

Reauthorization may be granted upon receipt of clinical documentation of improvement of asthma (i.e., decrease in oral steroid requirement, decrease in exacerbations, decreased asthma-related ED visits or hospitalizations) and CIU (i.e., decrease in antihistamine or steroid requirement, reduction in CIU flares).

**Limitations**

1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted based on diagnosis:
   a. Asthma: 12 months
   b. CIU: 6 months
3. Providers must confirm that Xolair will be administered only in a healthcare setting.

**References**

1. Xolair (omalizumab) [prescribing information]. San Francisco, CA: Genentech Inc; September 2018.


Review History
06/2003 - Implemented
09/26/05 - Reviewed/Updated
09/25/06 - Reviewed/Updated
09/24/07 - Reviewed/Updated
09/22/08 - Reviewed/Updated
09/21/09 - Reviewed/Updated
09/27/10 - Reviewed/Updated
09/19/11 - Reviewed/Updated
09/24/12 - Reviewed/Updated
09/23/13 - Reviewed/Updated
09/22/14 - Reviewed/Updated
09/21/15 - Reviewed/Updated
09/19/16 - Reviewed/Updated
09/18/17 - Reviewed/Updated
09/24/18 - Reviewed/Updated
09/18/19 - Deleted Leukine and spirometry requirement to align with MH

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