Antiasthmatic Monoclonal Antibodies –
Anti-IgE Antibodies

Medical policy no. 44.60.30-1  Effective Date: July 1, 2018
Related medical policies: Antiasthmatic Monoclonal Antibodies – IL-5 Antagonists (Medical policy no. 44.60.40)

Background:
Asthma is a common chronic inflammatory disease of the airways. For most patients asthma is well controlled with inhaled therapy but for those with severe asthma it can be associated with substantial morbidity, mortality, and economic effects.

Medical necessity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td>omalizumab (XOLAIR®)</td>
<td>Omalizumab (XOLAIR®) may be considered medically necessary when used for ONE of the following:</td>
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<tr>
<td></td>
<td>• Severe persistent allergic 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.</td>
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<tr>
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<td>• Chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.</td>
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Clinical policy:

Clinical Criteria

| Moderate to severe persistent allergic asthma | 1. Greater than or equal to (≥) 6 years of age
2. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to medium- to high-dose inhaled corticosteroids (ICS)
3. Positive skin test or in vitro reactivity to a perennial aeroallergen
4. Uncontrolled or inadequately controlled severe asthma is defined by at least ONE of the following:
   a. FEV₁, less than (<) 80% predicted
   b. Two or more bursts of systemic corticosteroids in the previous 12 months
   c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20)
5. Pre-treatment serum IgE level between 30 and 1500 IU/mL
6. Combination use with other monoclonal antibodies(e.g. benralizumab, mepolizumab, reslizumab) is considered not medically necessary |
7. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

Approve for 12 months

Criteria (Reauthorization)
Clinical documentation of disease stability or improvement compared to baseline measures.

Approve for 12 months

Chronic idiopathic urticaria
1. Greater than or equal to (≥) 12 years of age
2. History of failure, contraindication or intolerance to H1 antihistamine therapy
3. Combination use with other monoclonal antibodies (e.g. benralizumab, mepolizumab, reslizumab) is considered not medically necessary
4. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology

Approve for 12 months

Criteria (Reauthorization)
Clinical documentation of disease stability or improvement compared to baseline measures.

Approve for 12 months

Dosage and quantity limits

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose and Quantity Limits</th>
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<tbody>
<tr>
<td>omalizumab (XOLAIR®)</td>
<td>• Asthma: 375mg every 2 weeks</td>
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<td>• Urticaria: 300mg every 4 weeks; 2 vial per 28-day supply</td>
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Coding:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J2357</td>
<td>Injection, omalizumab, 5 mg</td>
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References


