Asthma/Allergy Immunomodulators Criteria

Indications:

Omalizumab is an anti-IgE antibody indicated for moderate to severe persistent asthma in patients 12 years and older inadequately controlled with inhaled corticosteroids or for chronic idiopathic urticaria.

Mepolizumab is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Reslizumab is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

Medications:

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dosage Strengths</th>
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</thead>
<tbody>
<tr>
<td>Xolair®</td>
<td>Omalizumab</td>
<td>150 mg/5ml vial</td>
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<tr>
<td>Nucala®</td>
<td>Mepolizumab</td>
<td>100mg powder for reconstitution</td>
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<tr>
<td>Cinqair®</td>
<td>Reslizumab</td>
<td>100mg/10ml vial</td>
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Criteria for Approval: ALL must be met

A. Prescriber is an Allergist, Immunologist or Pulmonologist (or one of these specialists has been consulted), AND
B. Patient is 12 years of age or older (Nucala® or Xolair®) or 18 years of age or older (Cinqair®), AND
C. Diagnosis of chronic idiopathic urticaria (for Xolair® only), OR
D. Diagnosis of moderate (for Xolair® only) or severe persistent asthma, AND
E. Inadequately controlled asthma despite medium to high doses of corticosteroid (inhaled or oral) in combination with:
   1. Long acting beta agonist, OR
   2. Leukotriene receptor agonist, OR
   3. Theophylline, AND
F. History of positive skin test or in vitro test to perennial aeroallergen or eosinophilic phenotype, AND
G. Non-smoker status, AND
H. Pre-treatment Serum immunoglobulin E (IgE) (IU/ml) level between 30 and 700 IU/ml (Xolair® only).

Approval Criteria for Renewal of 12 months:

A. Approved for initial 6 month trial, AND
B. Clinical improvement was seen

Criteria for Denial:

A. Above criteria are not met, OR
B. If being used for peanut allergy only, OR
C. Patient is an active smoker, OR
D. Failure to be compliant with current regimen as evidenced by review of claims history, OR
E. For asthma diagnosis only, no claims history of inhaled corticosteroid, long acting beta agonist, Leukotriene receptor, OR antagonists, or theophylline in the last 120 days for new prescriptions only

Length of Authorization: Initial 6 months, extended approval for 12 months if additional criteria are met.

References:
4. Xolair [package insert]. South San Francisco, CA; Genentech; December 2015.
5. Incorporating Anti-IgE (Omalizumab) Therapy Into Pulmonary Medicine Practice: Practice Management Implications: Philip Marcus; Chest. 2006;129:466-474.

<table>
<thead>
<tr>
<th>Reviewed by:</th>
<th>Reason for Review:</th>
<th>Date Approved:</th>
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<td>Pharmacy &amp; Therapeutic Committee</td>
<td>New</td>
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<td>9/29/06</td>
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