Xolair

Description

Xolair (omalizumab)

Background

Xolair is a monoclonal antibody that prevents binding of IgE to the high-affinity receptors on basophils and mast cells by forming complexes with circulating free IgE (1,2). It is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma whose symptoms are uncontrolled on inhaled corticosteroids (1). Xolair is a treatment option for patients with a pre-treatment IgE level of $\geq 30$ IU/mL with a positive skin test or in vitro reactivity to a perennial aeroallergen such as pollen, mold spores, dust mites, or animal allergens (2).

Current asthma guidelines state that Xolair may be considered as adjunctive therapy in patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose inhaled corticosteroids and long acting beta2-agonists, the preferred treatment for moderate persistent and severe persistent asthma (2). Alternative options include either a leukotriene modifier or theophylline in combination with inhaled corticosteroids for moderate persistent asthma (2).

Xolair has shown to be effective against allergy-induced asthma only. Allergy tests are required to identify patients who may be candidates for Xolair therapy. Allergic asthma is identified as testing positive to at least one perennial aeroallergen according to either a skin test (e.g. prick/puncture test, intracutaneous test) or a blood test (e.g. RAST) and having an IgE level between 30 and 700 IU/ml (1).
Xolair was evaluated in several clinical studies for safety and efficacy. Dosing was based on body weight and baseline serum IgE concentration (1).

**Regulatory Status**
FDA-approved indication: Xolair (omalizumab) is indicated for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair is also indicated for the treatment of adults and adolescents (12 years of age and above) with chronic idiopathic urticaria who remain symptomatic despite H1 antihistamine treatment (1).

**Limitations of use**:
- Not indicated for other allergic conditions
- Not indicated for acute bronchospasm or status asthmaticus
- Not indicated for pediatric patients less than 12 years of age

Xolair has a boxed warning of anaphylaxis after administration. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond 1 year after beginning regularly administered treatment. Due to the risk of anaphylaxis, patients should be observed closely for an appropriate period of time after Xolair administration. Health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair (1).

Malignant neoplasms were observed in 20 of 4127 (0.5%) Xolair-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents 12 years of age and older with asthma and other allergic disorders. The observed malignancies in Xolair-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to Xolair or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known (1).

Clinical studies with Xolair in pediatric patients less than 12 years of age have not been conducted (1).

**Related policies**
Nucala
Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xolair may be considered medically necessary in patients 12 years of age and older for the treatment of moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled after a minimum of 3 months with inhaled corticosteroids. The pre-treatment serum IgE must be within range based on patient's weight. Xolair has shown efficacy in patients with moderate-severe chronic idiopathic urticaria in patients who remained symptomatic despite H1-antihistamine therapy.

Xolair is considered investigational in patients under the age of 12 or in patients that do not have a positive skin prick test or RAST response to one allergen, or if no prior therapy of inhaled corticosteroids, or if the IgE level is outside of range based on patient's weight.

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Moderate or severe persistent Asthma

   AND ALL of the following:
   1. Positive skin prick test or RAST response to at least one common allergen
   2. Patient has symptoms that are inadequately controlled after a minimum of 3 months of inhaled corticosteroids
   3. Baseline serum IgE level between 30 -700 IU/mL

2. Chronic idiopathic urticaria
   a. In patients who remained symptomatic after previous trials of H1-antihistamines
Prior – Approval Renewal Requirements

Age  12 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Moderate to severe persistent asthma
   a. Patient has a documented response / improvement in symptoms
   b. Decreased utilization of rescue medications

   AND ONE of the following:
   1. NO interruptions in therapy 1 year or greater
      OR
   2. Interruption lasting one year or more require re-testing of total serum IgE levels
      a. Serum IgE level between 30-700 IU/mL

2. Chronic idiopathic urticaria
   a. Decrease in urticaria activity score (UAS)
      (such as: improvement in pruritic wheals, hives and itching)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration  12 months

Prior – Approval Renewal Limits

Duration  12 months

Rationale

Summary

Xolair has been shown to decrease the incidence of asthma exacerbations in adult and adolescent patients 12 years of age and older with moderate to severe persistent asthma who
have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to diminish clinical symptoms and signs of chronic idiopathic urticaria in patients who had remained symptomatic despite the use of approved doses of H1-antihistamines (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Xolair while maintaining optimal therapeutic outcomes.

References

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2009</td>
<td>Addition of RAST (radioallergosorbent test) as alternative when skin prick test is not feasible.</td>
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<tr>
<td></td>
<td>RAST often are used to test for allergies when:</td>
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<td></td>
<td>• a physician advises against the discontinuation of medications that can interfere with test results or cause medical complications;</td>
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<td></td>
<td>• a patient suffers from severe skin conditions such as widespread eczema or psoriasis</td>
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<td>• a patient has such a high sensitivity level to suspected allergens that any administration of those allergens might result in potentially serious side effects.</td>
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<tr>
<td>November 2010</td>
<td>Addition of serum IgE and weight limits to criteria based on the package insert dosing guidelines</td>
</tr>
<tr>
<td>September 2012</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>June 2013</td>
<td>Editorial review and strengthened renewal requirements</td>
</tr>
<tr>
<td>July 2014</td>
<td>Removal of serum IgE weight limits</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update. Addition of the 3 months of inhaled corticosteroids</td>
</tr>
<tr>
<td>March 2016</td>
<td>Annual editorial review</td>
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<td>Policy number change from 5.13.02</td>
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Keywords
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<td>Respiratory Agents</td>
<td>Original Policy Date:</td>
<td>December 1, 2009</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective on April 1, 2016.

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