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 patients 6 years of age and older 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 ≥ 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. 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 in patients 12 years of age and older and between 30 and 1300 IU/ml in patients between 6 and 11 years of age (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 an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment (1).

**Limitations of use:** (1)

- Not indicated for other allergic conditions or other forms or urticaria.
- Not indicated for acute bronchospasm or status asthmaticus.

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).

FEP adherence is defined as ≥50% utilization within the last 180 days.

Clinical studies with Xolair in pediatric patients less than 6 years of age have not been conducted (1).

**Related policies**

Cinqair, Dupixent, IL-5 Antagonists
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 6 years of age and older for the treatment of moderate to severe persistent asthma and in patients 12 years of age and older for the treatment of chronic idiopathic urticaria and if the conditions indicated below are met.

Xolair is considered investigational in patients under the age of 6 and for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have ONE of the following AND submission of medical records (e.g. chart notes, laboratory values) documenting the following:

1. Moderate or severe Asthma

AND ALL of the following:
   a. 6 years of age or older
   b. Positive skin prick test or RAST response to at least one common allergen
   c. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with ONE of the following within the past 6 months:
      i. Inhaled corticosteroids & long acting beta₂ agonist
      ii. Inhaled corticosteroids & long acting muscarinic antagonist
   d. Baseline serum IgE levels obtained:
      i. Baseline serum IgE level between 30 – 700 IU/mL for patients 12 years of age and older
      ii. Baseline serum IgE level between 30 – 1300 IU/mL for patients 6 years to 11 years of age
   e. NO dual therapy with another monoclonal antibody for the treatment of asthma
2. Chronic idiopathic urticaria
   a. 12 years of age or older
   b. Symptomatic after at least **TWO** previous trials of H1-antihistamines
   c. Baseline urticaria activity score (UAS)

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

**Prior – Approval Renewal Requirements**

**Diagnoses**

Patient must have **ONE** of the following **AND** submission of medical records (e.g. chart notes, laboratory values) documenting the following:

1. **Asthma**
   
   **AND ALL** of the following:
   a. 6 years of age or older
   b. Patient has a documented response / improvement in symptoms
   c. Decreased utilization of rescue medications
   d. **NO** dual therapy with another monoclonal antibody for the treatment of asthma

   **AND ONE** of the following:
   a. **NO** interruptions in therapy 1 year or greater
   b. Interruption lasting one year or more require re-testing of total serum IgE levels
      i. Serum IgE level between 30-700 IU/mL for patients 12 years of age and older
      ii. Serum IgE level between 30 – 1300 IU/mL for patients 6 years to 11 years of age.

2. **Chronic idiopathic urticaria**
   a. 12 years of age or older
b. Decrease in urticaria activity score (UAS), such as improvement in pruritic wheals, hives, and itching


All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval Renewal Limits

Same as above

Rationale

Summary

Xolair has been shown to decrease the incidence of asthma exacerbations in patients 6 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 12 years of age and older 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


<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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</thead>
<tbody>
<tr>
<td>December 2009</td>
<td>Addition of RAST (radioallergosorbent test) as alternative when skin prick test is not feasible. RAST often are used to test for allergies when: • a physician advises against the discontinuation of medications that can interfere with test results or cause medical complications; • a patient suffers from severe skin conditions such as widespread eczema or psoriasis • 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>
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<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>
</tr>
<tr>
<td></td>
<td>Policy number change from 5.13.02 to 5.45.02</td>
</tr>
<tr>
<td>September 2016</td>
<td>Annual editorial review and reference update. Addition of no dual therapy with another monoclonal antibody for asthma, change in age limit.</td>
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<tr>
<td>March 2017</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2018</td>
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<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td></td>
<td>Change in serum IgE level for patients 6 – 11 years of age to 30 – 1300 IU/mL for baseline in initiation and re-test in renewal (change from 30 – 700 IU/mL)</td>
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<td></td>
<td>Addition of 3 months of one of the following: Inhaled corticosteroids &amp; long acting beta₂ agonist or Inhaled corticosteroids &amp; long acting muscarinic antagonist</td>
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</tbody>
</table>
September 2018  Annual review and reference update
March 2019    Annual review and reference update
August 2019   Addition of the 50% adherence requirement to the asthma diagnosis.
              Addition to the managed PA program
September 2019 Annual review and reference update
October 2019  Addition of initial requirement for baseline urticaria activity score (UAS) and revised requirement to trial at least two H1-antihistamines
December 2019 Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.