Xolair® (omalizumab)

Policy Number: 5.02.503  Last Review: 08/2014
Origination: 08/2003  Next Review: 08/2015

Policy
BCBSKC will provide coverage for Xolair (omalizumab) when it is determined to be medically necessary because the following criteria have been met.

When Policy Topic is covered
Xolair requires prior authorization through the pharmacy services area.

Asthma
Xolair (omalizumab) will be considered for coverage for 1 year when the following criteria are met:
1) Patient is at least 12 years of age;
2) Diagnosis is moderate to severe persistent asthma;
3) Body weight is > 30 kg and < 150 kg;
4) Baseline serum total IgE level > 30 and < 700 IU/ml;
5) Evidence of specific allergic sensitivity to an airborne allergen;
6) Failure to respond to documented National Asthma Education and Prevention Program (NAEPP)¹ treatment for moderate persistent asthma:
   * moderate dose inhaled corticosteroid or
   * low-moderate dose inhaled corticosteroid and long-acting inhaled beta₂ agonist
   OR
7) Failure to respond to documented NAEPP treatment for severe persistent asthma
   * high dose inhaled steroid and long-acting inhaled beta₂ agonist

¹ http://www.nhlbi.nih.gov/guidelines/asthma/
Xolair (Omalizumab) is administered subcutaneously every 2 or 4 weeks. Doses (mg) and dosing frequency are determined by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). Dosages will be approved per the following schedule:

Table 1
ADMINISTRATION EVERY 4 WEEKS
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 4 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

<table>
<thead>
<tr>
<th>Pre-treatment Serum IgE (IU/mL)</th>
<th>30-60</th>
<th>&gt; 60-70</th>
<th>&gt; 70-90</th>
<th>&gt; 90-150</th>
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<tbody>
<tr>
<td>&gt;30-100</td>
<td>150</td>
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<td>&gt; 100-200</td>
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<td>&gt; 300-400</td>
<td>See Table 2</td>
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<td>&gt; 400-500</td>
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</tbody>
</table>

Table 2
ADMINISTRATION EVERY 2 WEEKS
Xolair Doses (milligrams) Administered by Subcutaneous Injection Every 2 Weeks for Adults and Adolescents (12 Years of Age and Older) with Asthma

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<thead>
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<th>&gt; 90-150</th>
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<tr>
<td>&gt;30-100</td>
<td>See Table 1</td>
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<td>&gt; 400-500</td>
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<td>375</td>
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<td>&gt; 500-600</td>
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<td>&gt; 600-700</td>
<td>375</td>
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</table>

Urticaria
Xolair will be considered for coverage of urticaria when the following criteria are met:

1. Patient is at least 12 years of age;
2. At least a 6 month history of urticaria and the presence of hives associated with itching despite an adequate trial (minimum 4 weeks) of:
   a. Two different high-dose H1-antihistamines (2 – 4 times normal dose daily dose) AND
   b. A high-dose H1-antihistamine (2 – 4 times normal dose daily dose) in combination with
leukotriene antagonist AND
  c. A high-dose H1-antihistamine (2 – 4 times normal dose daily dose) in combination with
cyclosporine, H2-antihistamine or Dapsone
3. Patient must have urticaria activity score (UAS7) during a 7-day period ≥16
4. Approved dose will be 150 to 300 mg SQ every 4 weeks for 3 doses (12 week approval)
5. Repeat courses after initial 12 week approval will only be granted if there is documentation of a
minimum 9.5 point improvement in UAS7 score with initial treatment course.
6. Not for use in patients weighing <20 kg or in patients who are pregnant

When Policy Topic is not covered
Xolair® (omalizumab) for other medical indications is considered investigational.

Considerations

Dosing Adjustments

Total IgE levels are elevated during treatment and remain elevated for up to one year after the
discontinuation of treatment. Therefore, re-testing of IgE levels during Xolair treatment cannot be used
as a guide for dose determination. Dose determination after treatment interruptions lasting less than 1
year should be based on serum IgE levels obtained at the initial dose determination. Total serum IgE
levels may be re-tested for dose determination if treatment with Xolair has been interrupted for one year
or more. Doses should be adjusted for significant changes in body weight.

This Blue Cross and Blue Shield of Kansas City policy was developed using available resources such
as, but not limited to: Hayes Medical Technology Directory, Food and Drug Administrative (FDA)
approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health
plans, Medicare (CMS), Local providers.

Description of Procedure or Service
Xolair (omalizumab) is a biologic drug classified as a monoclonal antibody. It selectively binds to
human immunoglobulin E (IgE). This action limits the degree of release of chemical mediators in the
body which cause an allergic response.

Xolair is indicated for patients 12 years 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 decrease the incidence
of asthma exacerbations in these patients. Safety and efficacy have not been established in other
allergic conditions.

Rationale

Asthma

Omalizumab increases the number of patients who are able to reduce or withdraw their inhaled steroids
and is effective in reducing asthma. [1,2,4,5]

Efficacy and dosing of omalizumab in patients with IgE levels greater than 700 have not been
established.

There is not data that omalizumab is superior to preferred options recommended in national treatment
guidelines for moderate to severe persistent asthma. [9,10, 14]

Omalizumab reduces seasonal and perennial allergic rhinitis symptoms, [3,6] but has not shown better
efficacy than first-line alternatives (such as nasal corticosteroids, antihistamines, or allergen
desensitization therapy). [8]
Strict compliance with omalizumab is necessary because of a 6-12 week lag before beneficial effects are apparent. (Effects are not immediate and explain the various phases that are included in study protocols).

Urticaria is the most frequent adverse effect reported with short-term therapy. [7] There have been some initial concerns with elevated risks of cancer with omalizumab, however, an independent committee of oncologists reviewed the data and were unable to establish a direct correlation. [12,13]

Phase II results (suggesting benefits of another anti-IgE compound-TNX-901) cannot be extrapolated to the use of omalizumab to protect against anaphylaxis in patients with peanut allergy. [11]

Urticaria

Emerging evidence supports the off-label use of omalizumab for urticaria. Omalizumab is currently classified as fourth-line therapy in the 2009 EAACI/GA(2)LEN/EDF/WAO guidelines. Efficacy for the treatment of urticaria has been confirmed in two small randomized controlled trials as well as in a number small cohorts, case series, and case reports.

References
17. Zuberbier T et al. EAACI/GA(2)LEN/EDF/WAO guideline: definition, classification and


Billing Coding/Physician Documentation Information

J2357 Injection, omalizumab, 5mg

Additional Policy Key Words

N/A

Related Topics

N/A

Policy Implementation/Update Information

08/2003 New policy titled Xolair (omalizumab)
08/2004 Reviewed – no changes made
08/2005 Reviewed – no changes made
01/2006 Revised – updated coding
08/2006 Reviewed – no changes made
08/2007 Reviewed – no changes made
08/2008 Reviewed – no changes made
08/2009 Reviewed – no changes made
08/2010 Reviewed – no changes made
08/2011 Reviewed – no changes made
08/2012 Reviewed – no changes made
08/2013 Revised to add off-label coverage for urticaria
08/2014 Revised to state urticaria is FDA approved indication

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