Xolair (omalizumab)

Line(s) of Business:  
HMO; PPO; QUEST Integration  
Akamai Advantage  
Original Effective Date:  
11/18/2003  
Current Effective Date:  
12/01/2017

POLICY
A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Asthma
Xolair is indicated for 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 decrease the incidence of asthma exacerbations in these patients.

Limitations of Use:
• Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus.
• Xolair is not indicated for treatment of other allergic conditions.

Chronic Idiopathic Urticaria (CIU)
Xolair is 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.

Limitation of Use: Xolair is not indicated for treatment of other forms of urticaria.

B. REQUIRED DOCUMENTATION
The following documentation from the medical record is necessary to initiate the prior authorization review:
• Allergic asthma, initial therapy:
  o Member age
  o Current medications (including doses)
  o Member current weight
  o Pre-treatment serum IgE (IU/mL) levels
  o Skin or blood test results confirming the diagnosis of allergic asthma
  o Clinical notes documenting failure of environmental controls and immune therapy
  o FEV1 results
  o Clinical notes documenting treatment of comorbidities
Chronic idiopathic urticaria (CIU), initial therapy:
  - Member age
  - Clinical notes supporting a diagnosis of CIU for at least 3 months
  - Clinical notes supporting trial and failure of all previous antihistamines, including length of courses

Allergic asthma, continuation of therapy:
  - Member age
  - Either comparative FEV1 results or Quality of Life Measures Survey
  - Current medications (including doses)

CIU, continuation of therapy:
  - Member age
  - Documentation supporting that the member has responded to therapy
  - For members demonstrating a complete response: documentation must support tapering of dose and/or withholding of therapy beyond the next dosing interval to see if symptoms return

C. PRESCRIBER RESTRICTION
   For allergic asthma, Xolair must be recommended by an allergist, immunologist, or pulmonologist.
   For CIU, Xolair must be recommended by an allergist, immunologist, or dermatologist.

D. INITIAL CRITERIA FOR APPROVAL

1. Allergic Asthma
   Authorization of 6 months may be granted to members who are prescribed Xolair when ALL of the following criteria are met:
   a. Prior to initiating therapy, the severity of the member’s asthma is moderate or severe persistent
   b. The member is 12 years of age or older
   c. Xolair will be administered in a controlled healthcare setting with access to emergency medications if needed
   d. The member’s asthma is inadequately controlled with the use of an inhaled corticosteroid at the optimized dose
   e. The member’s asthma is inadequately controlled with the use of a long acting beta agonist at the optimized dose
   f. The member’s current weight is less than or equal to 150 kg
   g. The member’s pre-treatment IgE level is greater than or equal to 30 IU/mL
   h. The prescribed Xolair dose follows FDA-approved dosing recommendations (for dose and dosing frequency) based on pre-treatment serum IgE levels and body weight (See prescribing information at www.xolair.com)
   i. Prior to initiating therapy, the member has positive skin or in vitro reactivity to at least one perennial aeroallergen
   j. The member has failed environmental controls and standard immune therapy, unless there is evidence that immune therapy will trigger a severe allergic reaction
   k. The member’s pre-treatment forced expiratory volume (FEV1) is less than 80% of predicted value
I. The member’s comorbidities have been evaluated and treated
m. The member has a rapid-acting beta₂ agonist available for rescue therapy
n. The member has completed a current HMSA Asthma Quality of Life Measures Survey

2. **Chronic idiopathic urticaria (CIU)**
   Authorization of 3 months may be granted to members who are prescribed Xolair when ALL of
   the following criteria are met:
   a. Prior to initiating therapy, the severity of the member’s CIU is moderate or severe
   b. The member is 12 years of age or older
   c. Xolair will be administered in a controlled healthcare setting with access to emergency
      medications if needed
   d. The member has been diagnosed with CIU for 3 months or longer
   e. The member has been evaluated for other causes of urticaria
   f. The member remained symptomatic despite treatment with at least 2 distinct courses of
      different high-dose second generation H1 antihistamines used continuously for at least 2
      weeks, unless contraindicated (See Appendix)
   g. The member remained symptomatic despite treatment with a first generation H1
      antihistamine (eg, hydroxyzine, doxepin) or an H2 antihistamine (eg, ranitidine) in
      combination with a high-dose second generation H1 antihistamine used continuously for at
      least 2 weeks, unless contraindicated (See Appendix)

E. **CONTINUATION OF THERAPY**
   1. No previous authorization/precertification:
      All members (including new members and members currently receiving treatment without prior
      authorization) must meet criteria for initial approval in section D. Those continuing with therapy
      must also meet Reauthorization criteria below.
   2. Reauthorization:
      A. **Allergic asthma**
         Authorization of 6 additional months may be granted to members who were previously
         authorized by HMSA when ALL of the following criteria are met. After the first year,
         authorization of 12 additional months may be granted to members when ALL of the
         following criteria are met:
         1) The member has shown improvement (or sustained improvement) in one of the
            following measures since initiation of Xolair therapy:
            i. Improvement in forced expiratory volume (FEV1)
            ii. Decrease in hospitalizations or emergency room visits
            iii. Overall increase in quality of life measures based on the HMSA Quality of Life
                urvey.pdf)
         2) The member will continue to use inhaled corticosteroids
      B. **Chronic idiopathic urticaria (CIU)**
         Authorization of additional 6 months may be granted to members who were previously
         authorized by HMSA when either criterion 1) or 2) below is met. After the first year,
authorization of 12 additional months may be granted to members when either criterion 1) or 2) below is met:

1) The member has demonstrated a partial response since initiation of Xolair therapy
2) The member has demonstrated a complete response since initiation of Xolair therapy AND symptoms returned when the dose was tapered or withheld beyond the next dosing interval

F. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. APPENDIX
High-dose second generation H1 antihistamines are defined as twice daily dosing of standard daily dosing (listed below):

- Cetirizine (Zyrtec\textsuperscript{®}) 10 mg
- Levocetirizine (Xyzal\textsuperscript{®}) 5 mg
- Fexofenadine (Allegra\textsuperscript{®}) 180 mg
- Loratadine (Claritin\textsuperscript{®}) 10 mg
- Desloratadine (Clarinex\textsuperscript{®}) 5 mg

H. ADMINISTRATIVE GUIDELINES
Prior authorization is required. Please refer to the HMSA medical policy web site for the fax form.

I. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

J. REFERENCES

Document History

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