Xolair (omalizumab)

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 information is necessary to initiate the prior authorization review:

For allergic asthma

- Initial therapy:
  - Member age
  - Current medications (including doses)
  - Member current weight
  - Pre-treatment serum IgE (IU/mL) levels
  - Skin or blood test results confirming the diagnosis of allergic asthma
  - Clinical notes documenting failure of environmental controls and immune therapy
  - FEV1 results
  - Clinical notes documenting treatment of comorbidities

- Continuation of therapy
  - Member age
  - Either comparative FEV1 results or Quality of Life Measures Survey
  - Current medications (including doses)

For chronic idiopathic urticaria:
- 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

- 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 6 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
l. 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 (available at https://www.hmsa.com/portal/provider/FM.Asthma_Quality_of_Life_Measures_Survey.pdf)

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.
   2. Reauthorization:
      A. **Allergic asthma**
         Authorization of an additional 6 months may be granted to members requesting authorization for continuation of therapy who meet ALL of the following criteria, and were previously authorized by HMSA/CVS. After the first year, authorization of an additional 12 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 Measures Survey (available at https://www.hmsa.com/portal/provider/FM.Asthma_Quality_of_Life_Measures_Survey.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 requesting authorization for continuation of therapy who meet either criterion 1) or 2) below, and were previously authorized by HMSA/CVS. After the first year, authorization of an additional 12 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®) 10 mg
- Levocetirizine (Xyzal®) 5 mg
- Fexofenadine (Allegra®) 180 mg
- Loratadine (Claritin®) 10 mg
- Desloratadine (Clarinex®) 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/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA 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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