

## SPECIALTY GUIDELINE MANAGEMENT

### XOLAIR (omalizumab)

#### POLICY

##### I. 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

###### A. Allergic Asthma:

1. 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.
2. Limitations of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.

###### B. Chronic Idiopathic Urticaria:

1. Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.
2. Limitations of use: Xolair is not indicated for treatment of other forms of urticaria.

All other indications are considered experimental/investigational and are not a covered benefit.

##### II. CRITERIA FOR INITIAL APPROVAL

###### A. Allergic Asthma

Authorization of 12 months may be granted for treatment of allergic asthma when ALL of the following criteria are met:

1. Member is 6 years of age or older
2. Member has a positive skin or in vitro reactivity to at least one perennial aeroallergen
3. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL
4. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
  - a. Inhaled corticosteroid
  - b. Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)

###### B. Chronic Idiopathic Urticaria

Authorization of 6 months may be granted for treatment of CIU when ALL of the following criteria are met:

1. Member is 12 years of age or older
2. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
3. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks

### III. CONTINUATION OF THERAPY

#### A. Allergic Asthma

Authorization of 12 months may be granted for treatment of allergic asthma when ALL of the following criteria are met:

1. Member is 6 years of age or older
2. Asthma control has improved on Xolair treatment as demonstrated by at least ONE of the following:
  - a. A reduction in the frequency or severity of symptoms and exacerbations, OR
  - b. An improvement in FEV<sub>1</sub> since initiation of therapy, OR
  - c. A reduction in the daily maintenance oral corticosteroid dose<sup>10</sup>

#### B. CIU

Authorization of 12 months may be granted for continuation of treatment of CIU when ALL of the following criteria are met:

1. Member is 12 years of age or older
2. Member has experienced a response (e.g., improved symptoms) since initiation of therapy

### IV. REFERENCES

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3. National Institutes of Health. *National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007*. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. <http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf>. Accessed March 2, 2017.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2017 update. <http://ginasthma.org/2017-gina-report-global-strategy-for-asthma-management-and-prevention/>. Accessed March 2, 2017.
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6. Kew KM, Karner C, Mindus SM. Combination formoterol and budesonide as maintenance and reliever therapy versus combination inhaler maintenance for chronic asthma in adults and children (review). *Cochrane Database Syst Rev*. 2013;12:CD009019.
7. Zuberbier T, Asero R, Bindslev-Jensen C, et al. EAACI/GA<sup>2</sup>LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria: the 2013 revision and update. *Allergy*. 2014;69:868-887.
8. Bernstein DI, Blessing-Moore J, Cox L, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. *American Academy of Allergy, Asthma & Immunology Practice Parameter*. <http://www.aaaai.org/practice-resources/statements-and-practice-parameters/practice-parameter-guidelines.aspx>. Accessed March 6, 2017.
9. Maurer M, Rosen K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013;368(10):924-935.