Reference number(s)
1656-A

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
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.

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 (CIU)
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.

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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Asthma: Member's chart or medical record showing pre-treatment IgE level (initial request only)
B. CIU: Member's chart or medical record showing an inadequate treatment response to a second-generation H1 antihistamine (initial request only)

III. CRITERIA FOR INITIAL APPROVAL

A. Asthma
Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:
1. Member is 6 years of age or older.
2. Member has a positive skin test 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 (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
   a. Inhaled corticosteroid

b. Additional controller (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

5. Member will not use Xolair as monotherapy.
6. Member does not currently smoke.
7. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).

B. Chronic idiopathic urticaria

Authorization of 6 months may be granted for treatment of chronic idiopathic urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member remains symptomatic despite treatment with a second-generation H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks.
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis).
4. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks.

IV. CONTINUATION OF THERAPY

A. Asthma

Authorization of 12 months may be granted for treatment of 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 and/or severity of symptoms and exacerbations
   b. A reduction in the daily maintenance oral corticosteroid dose
3. Member will not use Xolair as monotherapy.
4. Member does not currently smoke.
5. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).

B. Chronic idiopathic urticaria

Authorization of 12 months may be granted for continuation of treatment of chronic idiopathic urticaria 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, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy.

V. REFERENCES

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; September 2018.
2. 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 18, 2019.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018 update. http://ginasthma.org/2018-gina-report-global-strategy-for-asthma-management-and-prevention/. Accessed March 18, 2019.
4. Strunk RC, Bloomberg GR. Omalizumab for asthma. *N Engl J Med.* 2006;354(25):2689-2695.

5. 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.
6. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA^{2}LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy.* 2018;73(7):1393-1414. doi: 10.1111/all.13397.
7. 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 21, 2019.
8. 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.