

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

\*FHK- Florida Healthy Kids

## Xolair (omalizumab)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Xolair (omalizumab)

### APPROVAL CRITERIA

Initial requests for Xolair (omalizumab) for moderate to severe persistent asthma may be approved if the following criteria are met:

- I. Individual is 6 years of age or older; **AND**
- II. Individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (medium to high dose inhaled corticosteroids plus long acting beta-2 agonists or leukotriene modifiers) (GINA 2018); **AND**
- III. Individual has a positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
- IV. Individual has a forced expiratory volume in one second (FEV<sub>1</sub>) less than 80% predicted; **AND**
- V. A serum Immunoglobulin E (IgE) level is equal to or greater than 30 IU/mL.

Continuation requests for Xolair (omalizumab) for moderate to severe persistent asthma may be approved if the following criteria are met:

- I. Treatment with Xolair (omalizumab) has resulted in clinical improvement as confirmed by one or more of the following:
  - A. Decreased utilization of rescue medications; **OR**
  - B. Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
  - C. Increase in percent predicted FEV<sub>1</sub> from pretreatment baseline; **OR**
  - D. Reduction in reported asthma-related symptoms, such as, but not limited to, wheezing, shortness of breath, coughing, fatigue, sleep disturbance, or asthmatic symptoms upon awakening.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Requests for Xolair (omalizumab) for chronic idiopathic urticaria (CIU) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older; **AND**
- II. Individual has had a trial and inadequate response or intolerance to H<sub>1</sub> antihistamines, H<sub>2</sub> antihistamines and leukotriene receptor antagonists (AAAAI/ACAAI 2014).

**Note:** Xolair carries a black box warning for anaphylaxis. Anaphylaxis has been reported after the first dose of Xolair but also beyond one year after beginning treatment. Individuals should be closely observed after Xolair administration as well as informed of signs and symptoms of anaphylaxis and to seek care immediately should symptoms occur.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Bernstein JA, Lang DM, Khan DA, et al. Joint Task Force on Practice Parameters (JTFPP), representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology. Practice parameter: the diagnosis and management of acute and chronic urticaria: 2014 update. J Allerg Clin Immunol. 2014; 133(5):1270-1277.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 20, 2018.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2018. Available from: <http://ginasthma.org/gina-reports/>. Accessed on: June 20, 2018.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
7. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. NIH Publication Number 08-5846. October 2007. Available at: <http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf>. Accessed: June 20, 2018.

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