| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

# Xolair (omalizumab)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | Initial Requests: 6 months<br>Continuation Requests: 1 year |

| Medications | Dosing Limit |
|---|---|
| Xolair (omalizumab) 150 mg vial & 75 mg and 150 mg syringes | 375 mg as frequently as every 2 weeks |

## APPROVAL CRITERIA

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

I. Individual is 6 years of age or older; **AND**
II. Individual has a diagnosis of moderate to severe persistent asthma; **AND**
III. Individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting beta$_2$-agonists, leukotriene modifiers, theophylline or oral corticosteroids) (GINA 2019); **AND**
IV. Individual has a positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
V. Individual has a pretreatment forced expiratory volume in 1 second ($FEV_1$) less than 80% predicted; **AND**
VI. 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 $FEV_1$ 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.

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

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 a diagnosis of chronic idiopathic urticaria (CIU); **AND**
III. Individual has had a trial and inadequate response or intolerance to $H_1$ antihistamines, $H_2$ antihistamines **AND** leukotriene receptor antagonists (AAAAI/ACAAI 2014).

Continuation requests for Xolair (omalizumab) for chronic idiopathic urticaria (CIU) may be approved if the following criterion is met:

I. Treatment with Xolair has resulted in confirmed clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to itch severity and hive count).

Xolair (omalizumab) may not be approved when the above criteria are not met and for all other indications.

**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.

**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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 8, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available from: http://ginasthma.org/gina-reports/. Accessed on: January 9, 2020.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
6. National Asthma Education and Prevention Program (NAEPP). Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. NIH Publication Number 08-5846. Updated: August 5, 2008. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm. Accessed: January 9, 2020.




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.

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | NA |

7. Wenzel S. Treatment of severe asthma in adolescents and adults. Last updated: November 13, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: January 30, 2020.