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**Drug Class Prior Authorization Criteria**  
**Xolair (Omalizumab)**

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**Line of Business:** Medicaid

**P & T Approval Date:** May 5, 2023

**Effective Date:** June 2, 2023

*This drug class prior authorization criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.*

**CRITERIA:**

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**Covered Uses:** \*Moderate to severe persistent asthma  
(\*Subject to review by a Clinical Pharmacist)

**Exclusion Criteria:** N/A

**Required Medical Information:** Must meet all of the following requirements:

- a. Diagnosis confirmed by "1" of the following:
  - i. Documented positive skin test
  - ii. In vitro reactivity to a year-round airborne substance (e.g., perennial aeroallergen) such as pollen or spores that triggers an allergic reaction
- b. Serum IgE level greater than or equal to 30 IU/mL
- c. Documentation of inadequate symptoms control with regular use of a combination of high dose inhaled corticosteroids (ICS) and a long acting beta<sub>2</sub>-agonist (LABA)
- d. Documentation of symptomatic asthma despite regular use of tried therapies as demonstrated by "1" of the following:
  - i. 2 or more exacerbations in the past 12 months (i.e., sudden worsening of asthma symptoms including shortness of breath, coughing, wheezing, etc.) requiring a course of systemic corticosteroids (e.g., prednisone)
  - ii. Hospitalization due to an asthma exacerbation
  - iii. Forced expiratory volume in one second (FEV<sub>1</sub>) less than 80% predicted

**Age Restrictions:** Must be 6 years of age or older

**Prescriber Restrictions:** Allergist, Immunologist or Pulmonologist

**Other Criteria:** Reauthorization criteria: Must meet all of the following:

- a. Documentation of meeting therapeutic goal as demonstrated by “1” of the following:
  - i. Decreased rescue medication (e.g., albuterol) utilization
  - ii. Decreased frequency of asthma attacks (e.g., systemic corticoid utilization, hospitalization, etc.)
  - iii. Improved percent predicted FEV<sub>1</sub> from pretreatment baseline (e.g., at least 5% improvement)
  - iv. Reduction of asthma-related symptoms including but not limited to wheezing, shortness of breath, coughing, fatigue or asthmatic symptoms upon awakening
- b. Used in combination with an inhaled corticosteroid controller medication
- c. Requested dosage and administration are consistent with the FDA recommendation

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**Covered Uses:** \*Chronic idiopathic urticaria  
(\*Subject to review by a Clinical Pharmacist)

**Exclusion Criteria:** N/A

**Required Medical Information:** Must meet all of the following requirements:

- a. Documentation of hives (e.g., urticaria) that has been intermittently or continuously present for at least 6 weeks
- b. Must meet “1” of the following requirements:
  - i. Failure or clinically significant adverse effects to at least a 2-week trial of “2” different second generation H1-antihistamines (e.g., fexofenadine, cetirizine, loratadine) at maximally tolerated dose
  - ii. Failure or clinically significant adverse effects to a combination of “1” second generation H1-antihistamine with “1” of the following:
    - 1. H2-antihistamine (e.g., famotidine)
    - 2. Leukotriene modifier (e.g., montelukast)
- c. Documentation of continued use of a second generation H1-antihistamine, unless intolerant or contraindicated
- d. Member is symptomatic with above therapies (i.e., persistent skin lesions despite maximum FDA-approved dose of antihistamine)

**Age Restrictions:** Must be 12 years of age or older

**Prescriber Restrictions:** Allergist, Immunologist or Dermatologist

**Other Criteria:** Reauthorization criteria: Must meet the following requirement:

- a. Documentation of meeting therapeutic goals (e.g., reduction in hives improved skin condition, etc.)

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**References:**

1. California Department of Health Care Services. Medi-Cal Provider Manual: Injections, Drugs N-R Policy (inject drug n-r). Accessed April 13th, 2023.
  2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. <http://www.ginasthma.org>. Accessed April 5th, 2023.
  3. Xolair (omalizumab) [package insert]. South San Francisco, CA. Genentech. Revised July 2021. Accessed April 13th, 2023.
  4. Zuberbier, T, Abdul Latiff, AH, Abuzakouk, M, et al. The international EAACI/GA<sup>2</sup>LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022; 77: 734– 766. doi:10.1111/all.15090. Accessed April 13th, 2023.
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Change Control		
Date	Change	RPH
05/05/2023	<ul style="list-style-type: none"><li>• Updated References</li></ul>	TL, SV
05/04/2022	<ul style="list-style-type: none"><li>• Removed ranitidine as an example of a H2-antihistamine</li></ul>	YA
02/05/2021	<ul style="list-style-type: none"><li>• Renew with no changes</li></ul>	ND
02/19/2020	<ul style="list-style-type: none"><li>• Renew with no changes</li></ul>	CN
02/20/2019	<ul style="list-style-type: none"><li>• Added (*Subject to review by a Clinical Pharmacist) to covered uses</li><li>• Changed diagnosis to covered uses for consistency</li><li>• Updated the criteria language for chronic idiopathic urticaria per 2018 EAACI/GA<sup>2</sup>LEN/EDF/WAO guidelines. Updated therapeutic requirements to meet “1” of two options: failure of two different second generation H1-antihistamines or failure of one second generation H1-antihistamine in combination with one of the following: H2-antihistamine or leukotriene modifier</li><li>• Added references</li></ul>	IK
11/29/2018	<ul style="list-style-type: none"><li>• Reformatted to align with current layout</li></ul>	IK
02/21/2018	<ul style="list-style-type: none"><li>• Added dermatologist to specialty for urticaria indication</li></ul>	CT