

<b>Policy Title:</b>	Xolair (omalizumab) (subcutaneous)		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	12/18/2018, 12/20/2019		
<b>Revision Date:</b>	12/18/2018, 12/20/2019		

**Purpose:** To support safe, effective and appropriate use of Xolair (omalizumab).

**Scope:** Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

**Policy Statement:**

Xolair (omalizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

**Procedure:**

Coverage of Xolair (omalizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**

**Asthma**

- Member is 6 years of age or older; AND
- Xolair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Member weighs between 20 kg (44 lbs) and 150 kg (330 lbs); AND
- Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen; AND
- Member has documentation of pre-treatment IgE level of either:
  - $\geq 30$  IU/mL and  $\leq 700$  IU/mL in members 12 years of age and older; OR
  - $\geq 30$  IU/mL and  $\leq 1300$  IU/mL in members age 6 to < 12 years; AND
- Member has documentation of moderate or severe asthma (see Appendix); AND
- Member is adherent to current treatment with both of the following medications at optimized doses
  - Inhaled corticosteroid; AND
  - Additional controller (long acting beta<sub>2</sub>-agonist, leukotriene modifier, or sustained-release theophylline); AND
- Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations); AND
- Member will use Xolair as add-on maintenance treatment; AND

- Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala)

### **Chronic idiopathic urticaria**

- Member is 12 years of age or older; AND
- Xolair is prescribed by, or in consultation with, an allergist/immunologist or dermatologist; AND
- Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis), and is not considered to have any other form(s) of urticaria; AND
- Member is avoiding triggers (e.g., NSAIDs, etc.); AND
- Member's baseline documentation score from an objective clinical evaluation tool, such as urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL), is provided; AND
- Member has had an inadequate response to therapy with scheduled dosing of a second-generation H<sub>1</sub> antihistamine for at least one month; AND
- Member has had an inadequate response to previous therapy with scheduled dosing of one of the following:
  - Updosing/dose advancement (up to 4-fold) of a second-generation H<sub>1</sub> antihistamine
  - Add-on therapy with a leukotriene antagonist (e.g., montelukast)
  - Add-on therapy with another H<sub>1</sub> antihistamine
  - Add-on therapy with a H<sub>2</sub>-antagonist; AND
- Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks

### ***Continuation of Therapy Criteria:***

#### **Asthma**

- Member is 6 years of age or older; AND
- Xolair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Member weighs between 20 kg (44 lbs) and 150 kg (330 lbs); AND
- Member is tolerating treatment; AND
- Documentation of asthma control has improved/stabilized on Xolair treatment from baseline as demonstrated by at least one of the following:
  - A reduction in the frequency and/or severity of symptoms and exacerbations; OR
  - A reduction in the daily maintenance oral corticosteroid dose; AND
- Member will use Xolair as add-on maintenance treatment; AND
- Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Nucala).

### **Chronic idiopathic urticaria**

- Member is 12 years of age or older; AND
- Xolair is prescribed by, or in consultation with, an allergist/immunologist or dermatologist; AND
- Member is tolerating treatment; AND
- Member has experienced clinical improvement since initiation of Xolair therapy as documented by improvement from baseline using an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL)

### **Coverage durations:**

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

\*\*\* Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.\*\*\*

### **Dosage/Administration:**

<b>Indication</b>	<b>Dose</b>	<b>Maximum dose (1 billable unit = 5 mg)</b>
Allergic Asthma	75 to 375 mg administered subcutaneously by a health care provider every 2 or 4 weeks	90 billable units every 14 days
Chronic idiopathic urticaria	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks	60 billable units every 28 days

### **Appendix:**

**Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):**

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

**Components of Severity for Classifying Asthma as Moderate may include any of the following (not all inclusive):**

1. Daily symptoms
2. Nighttime awakenings >1x/week but not nightly
3. SABA use for symptom control occurs daily
4. Some limitation to normal activities
5. Lung function (percent predicted FEV1) >60%, but <80%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2357	Injection, omalizumab, 5 mg

**References:**

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6. Maurer M, Rosén K, Hsieh HJ, et al. Omalizumab for the treatment of chronic idiopathic or spontaneous urticaria. *N Engl J Med*. 2013 Mar 7;368(10):924-35. doi: 10.1056/NEJMoa1215372. Epub 2013 Feb 24.
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