Policy Title:	Xolair (omalizumab) (subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/18/2018, 12/20/2019, 1/29/20		
Revision Date:	12/18/2018, 12/20/2019, 1/29/20		

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:

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements;

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:
    - ≥ 30 IU/mL and ≤ 700 IU/mL in members 12 years of age and older; OR
    - ≥ 30 IU/mL and ≤ 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 $beta_2$-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_1 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_1 antihistamine
    - Add-on therapy with a leukotriene antagonist (e.g., montelukast)
    - Add-on therapy with another H_1 antihistamine
    - Add-on therapy with a H_2-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:

Indication	**Dose**	**Maximum dose (1 billable unit = *5* mg)**
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:

1. Xolair [package insert]. South San Francisco, CA; Genentech, Inc.; September 2018. Accessed October 2018.

2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA).Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: http://www.ginasthma.org. Accessed April 2018.
4. Baiardini I, Braido F, Bindslev-Jensen C, et al. Recommendations for assessing patientreported outcomes and health-related quality of life in patients with urticaria: a GA (2) LEN taskforce position paper. Allergy. 2011 Jul;66(7):840-4. doi: 10.1111/j.1398- 9995.2011.02580.x. Epub 2011 Mar 9.
5. Zuberbier T, Aberer W, Asero R, et al. EAACI/GA (2) LEN/EDF/WAO guideline for the Definition, Classification, Diagnosis and Management of Urticaria. The 2017 Revision and Update.. Allergy. 2018 Jan 15. doi: 10.1111/all.13397.
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.
7. Siles RI, Hsieh FH. Allergy blood testing: A practical guide for clinicians. Cleve Clin J Med. 2011 Sep;78(9):585-92. doi: 10.3949/ccjm.78a.11023.
8. Bernstein JA, Lang DM, Khan DA, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. J Allergy Clin Immunol. 2014 May;133(5):1270-7.
9. Wisconsin Physician Service Insurance Corp. Local Coverage Determination (LCD): Drugs and Biologics (Non-chemotherapy) (L34741). Centers for Medicare & Medicare Services. Updated on 3/20/2018 with effective dates 4/01/2018. Accessed April 2018.
10. First Coast Service Options, Inc. Local Coverage Determination (LCD): Omalizumab (Xolair) (L33924). Centers for Medicare & Medicare Services. Updated on 09/03/2014 with effective dates 10/01/2015. Accessed April 2018.
11. National Government Services, Inc. Local Coverage Article: Omalizumab (e.g., Xolair) – Related to LCD L33394 (A52448). Centers for Medicare & Medicare Services. Updated on 12/24/2015 with effective dates 10/01/2015. Accessed April 2018