Policy Title:	Xolair (omalizumab) (subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/18/2018, 12/20/2019, 1/29/20, 1/11/2021, 5/13/2021, 9/02/2021, 1/06/2022		
Revision Date:	12/18/2018, 12/20/2019, 1/29/20, 1/11/2021. 5/13/2021, 9/02/2021, 1/06/2022		

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

Scope: Medicaid, Commercial, 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;

Must not be used in combination with another anti-IL4 or anti-IL5 monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab, dupilumab, etc.)

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

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 (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) 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 (e.g., cetirizine, fexofenadine, levocetirizine, loratadine)
    - antihistamine
    - Add-on therapy with a leukotriene antagonist (e.g., montelukast)
    - Add-on therapy with another H_1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine, diphenhydramine, hydroxyzine)
    - 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

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Member is at least 18 years of age; AND
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; AND
- Patient has failed at least 8 weeks of daily intranasal corticosteroid therapy; AND

- Patient meets ONE of the following:
    - Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
    - Patient has a contraindication to systemic corticosteroid therapy; OR
    - Patient has had prior surgery for nasal polyps; AND

- Patient does not have any of the following:
    - Antrochoanal polyps
    - Nasal septal deviation that would occlude at least one nostril
    - Disease with lack of signs of type 2 inflammation
    - Cystic fibrosis
    - Mucoceles; AND
- Other causes of nasal congestion/obstruction have been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis, etc.); AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Therapy will be used in combination with intranasal corticosteroids unless not able to tolerate or is contraindicated

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)

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool (e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sino-nasal outcome test-22 (SNOT-22), etc.).

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 §§ The pre-filled syringe formulation may be self-administered after the initial 3	90 billable units every 14 days

	doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below.	
Chronic idiopathic urticaria	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks §§ The pre-filled syringe formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below.	60 billable units every 28 days
Nasal polyps	75 to 600 mg administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See table below. §§ The pre-filled syringe formulation may be self-administered after the initial 3 doses are administered in the healthcare setting AND the healthcare provider determines that self-administration is appropriate based on assessment of risk for anaphylaxis and mitigation strategies. See criteria below.	120 billable units every 14 days

Criteria for Selection of Patients for Self-Administration of Xolair Prefilled Syringe §§
• Patient should have no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc.; AND • Patient should receive at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions; AND • Patient or caregiver is able to recognize symptoms of anaphylaxis; AND • Patient or caregiver is able to treat anaphylaxis appropriately; AND • Patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen and Instructions for Use
Note: Xolair prefilled syringes for patients under 12 years of age should be administered by a caregiver.

Appendix:

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

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- Short-acting beta agonist (SABA) use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- 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):

- Daily symptoms
- Nighttime awakenings >1x/week but not nightly
- SABA use for symptom control occurs daily
- Some limitation to normal activities
- Lung function (percent predicted FEV1) >60%, but <80%
- 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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