Effective Date: 01/01/2020
Reviewed: 12/18, 12/19, 1/20, 1/21, 5/21, 9/21, 1/22, 1/23, 01/24, 05/24
Pharmacy Scope: Medicaid
Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Xolair (omalizumab)

Policy Statement:

Xolair (omalizumab) is covered under the Pharmacy Benefit for Medicaid members and covered under the Medical Benefit for Medicaid, Commercial and MMP members 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.

Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

Asthma:

- Initial requests: documentation of pre-treatment IgE level, weight and components of severity that classify asthma as moderate or severe
- Continuation of therapy requests: documentation of weight and improved asthma control.

CIU:

- Initial requests: Member's baseline documentation of baseline scores 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), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-QoL) and documentation of an inadequate treatment response to pharmacological management.
- Continuation of therapy requests: documented score from an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q_2oL, etc.) recorded within the previous 6 months.

CRSwNP:

- Initial requests: documentation of indicators for biologic treatment and baseline disease severity
- Continuation of therapy requests: documentation of beneficial response to treatment

IgE-mediated food allergy:

- Initial requests: Chart notes, medical record documentation, or laboratory tests showing the following (if applicable):
  - Pre-treatment allergen-specific IgE level
  - Skin-prick test wheal diameter
  - Pre-treatment serum IgE level
  - Positive result of a physician controlled oral food challenge
  - History of a systemic reaction to a food
- Continuation requests: Chart notes or medical record documentation supporting positive response to therapy (e.g., decrease in hypersensitivity to food-allergen).

Initial Criteria:

- Must not be used in combination with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenra, Nucala, Xolair, Tezspire)

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, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated 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
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids

  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV_1)
- Member will use Xolair as add-on maintenance treatment
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (*other than indicated*).

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)), urticaria control test (UCT), angioedema control test (AECT), 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 a one month or more trial on 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

  Note: renewals will require a documented score from an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q_2oL, etc.) recorded within the previous 6 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Member is at least 18 years of age; AND
- Member has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; AND
- Member has failed at least 8 weeks of daily intranasal corticosteroid therapy; AND
- Member meets ONE of the following:
    - Member has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR
    - Member has a contraindication to systemic corticosteroid therapy; OR
    - Member has had prior surgery for nasal polyps; AND
- Member 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

IgE-mediated food allergy:

- Member is at least 1 year of age**;** AND
- Xolair is prescribed by, or in consultation with, an allergist/immunologist; AND
- Member is avoiding known food allergens; AND
- Member is allergic to peanut and at least one other food (e.g., milk, egg, wheat, tree nuts, etc.); AND
- Member's allergy must be confirmed by <u>all</u> of the following:
    - Positive skin prick test (SPT), defined as wheal ≥4 mm larger than saline control
    - Positive peanut and food specific IgE, defined as ≥6 IU/mL at screening or within three months of screening

- Positive double-blind placebo-controlled food challenge (DBPCFC), defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg of peanut protein and ≤300 mg of food protein; AND

- Will not be used for the emergency treatment of allergic reactions, including anaphylaxis

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.).

IgE-mediated food allergy:

- Member is at least 1 year of age; AND
- Xolair is prescribed by, or in consultation with, an allergist/immunologist; AND
- Provider attests that the patient has been reassessed and continued therapy is necessary for the maintenance treatment of this condition; AND
- Patient has had a reduction in allergic reaction, including anaphylaxis, and/or symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms) associated with accidental exposure of known food allergens; AND
- Member will continue to maintain a food-allergen avoidance diet.

Coverage durations:

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

Quantity Limit (Pharmacy Benefit)

- Xolair 75mg/0.5 ml syringe - 2 syringes per 28 days
- Xolair 150mg/ml syringe – 8 syringes per 28 days
- Xolair 150mg vial – 8 vials per 28 days
- Xolair 300mg/2ml syringe and autoinjector - 4 syringes/autoinjectors per 28 days

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	75 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

Nasal polyps	75 to 600 mg administered subcutaneously by a health care provider every 2 or 4 weeks. .	120 billable units every 14 days
IgE-mediated food allergy	75 to 600 mg administered subcutaneously by a health care provider every 2 or 4 weeks.	60 billable units every 28 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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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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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