Xolair® (omalizumab)
(Subcutaneous)

Document Number: IC-0146

Last Review Date: 08/03/2021
Date of Origin: 01/01/2012
Dates Reviewed: 06/2012, 02/2013, 04/2014, 09/2014, 07/2015, 07/2016, 09/2016, 12/2016, 03/2017, 06/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018, 10/2019, 10/2020, 12/2020, 01/2021, 05/2021, 08/2021

I. Length of Authorization

Coverage will be provided for six months and may be renewed, unless otherwise specified.

- Management of Immune Checkpoint Inhibitor-Related Toxicity may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xolair 75 mg single-dose prefilled syringe: 1 syringe every 14 days
- Xolair 150 mg single-dose prefilled syringe: 4 syringes every 14 days
- Xolair 150 mg powder for injection: 4 vials every 14 days

B. Max Units (per dose and over time) [HCPCS Unit]:

Allergic Asthma
- 90 billable units every 14 days

CRSwNP
- 120 billable units every 14 days

All other indications
- 60 billable units every 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age (unless otherwise specified); **AND**

Universal Criteria [1]

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

Moderate-to-severe persistent allergic asthma † [1-3,20]

- Patient is at least 6 years of age; **AND**
- Will not be used for treatment of acute bronchospasm, status asthmaticus, or allergic conditions (*other than indicated*); **AND**
- Patient has a positive skin test or in vitro reactivity to a perennial aero-allergen; **AND**
- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
- Patient has a serum total IgE level, measured before the start of treatment, of either:
  - ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years; **OR**
  - ≥ 30 IU/mL and ≤ 1300 IU/mL in patients age 6 to <12 years; **AND**
- Patient has documented ongoing symptoms of moderate-to-severe asthma***** with a minimum (3) month trial on previous combination therapy including medium- or high-dose inhaled corticosteroids **PLUS** another controller medication (e.g., long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline, etc.); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of inhaled rescue medication
  - Use of inhaled or systemic corticosteroids
  - Reported disease severity symptoms (e.g., number of hospitalizations, ER visits, unscheduled visits to healthcare provider due to condition, asthma attacks, chest tightness or heaviness, coughing or clearing throat, difficulty taking deep breath or difficulty breathing out, shortness of breath, sleep disturbance, night wakening, or symptoms upon awakening, tiredness, wheezing/heavy breathing/fighting for air, etc.)
  - Forced expiratory volume in 1 second (FEV_1)

Chronic idiopathic urticaria (CIU) † [1,4-6,8]

- Patient is at least 12 years of age; **AND**
- The underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; **AND**
- Patient is avoiding triggers (e.g., NSAIDs, etc.); **AND**
- Documented baseline 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-Q_2oL); **AND**
- Patient had an inadequate response to a one or more month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product******; **AND**
- Patient had an inadequate response to a one or more month trial on previous therapy with scheduled dosing of at least one of the following:
  - Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine******
  - Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)
  - Add-on therapy with another H1-antihistamine******

- Add-on therapy with a H2-antagonist (e.g. ranitidine, etc.)
- Add-on therapy with cyclosporine

Note: renewal will require submission of a current (within 30 days) score from an objective clinical evaluation tool (i.e., UAS7, AAS, DLQI, AE-QoL or CU-Q_2oL).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † [1,22,23]

- 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 has at least four (4) of the following indicators for biologic treatment *[Note: Patients with a history of sino-nasal surgery are only required to have at least three (3) of the indicators]:*
    - Patient has evidence of type 2 inflammation (i.e., biological biomarkers indicating immune dysregulation and epithelial barrier dysfunction)
    - Patient has required two or more short courses of systemic corticosteroids within the previous year
    - Disease significantly impairs the patient's quality of life
    - Patient has experienced significant loss of smell
    - Patient has a comorbid diagnosis of asthma; **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

Management of Immune Checkpoint Inhibitor-Related Toxicity ‡ [9,10]

- Patient has been receiving therapy with an immune checkpoint inhibitor (e.g. nivolumab, pembrolizumab, atezolizumab, avelumab, durvalumab, cemiplimab, ipilimumab, etc.); **AND**
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritis; **AND**

- Patient has an increased serum IgE level above the upper limit of normal of the laboratory reference value

Systemic Mastocytosis ‡ [9,11]

- Used for the prevention of one of the following:
  - Chronic mast cell mediator-related cardiovascular (e.g., pre-syncope, tachycardia, etc.) or pulmonary (e.g., wheezing, throat-swelling, etc.) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids); **OR**
  - Unprovoked anaphylaxis; **OR**
  - Hymenoptera or food-induced anaphylaxis in patients with a negative test for specific IgE antibodies or a negative skin test; **OR**
- Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT])

***Components of severity for classifying asthma as moderate may include any of the following (not all inclusive): [2]**
• 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 FEV_1) >60%, but <80% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma
***Components of severity for classifying asthma as severe may include any of the following (not all inclusive): [2]**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times daily • Extremely limited in normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma
****H1 Antihistamine Products (not all inclusive) [5,8]**
• fexofenadine • loratadine • desloratadine • cetirizine • levocetirizine • clemastine • diphenhydramine • chlorpheniramine • hydroxyzine • cyproheptadine • brompheniramine • triprolidine • dexchlorpheniramine • carbinoxamine

† FDA-approved indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria [1,10,11,22,23]

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever, arthralgia, and rash), parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids), etc.; **AND**

Moderate-to-severe persistent allergic asthma

- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
- Treatment has resulted in clinical improvement as documented by one or more of the following:
  - Decreased utilization of rescue medications; **OR**
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
  - Improvement in lung function (increase in percent predicted FEV_1 or PEF) from pre-treatment baseline; **OR**
  - Reduction in reported disease severity symptoms as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
    - Hospitalizations, ER visits, unscheduled visits to healthcare provider
    - Asthma attacks
    - Chest tightness or heaviness
    - Coughing or clearing throat
    - Difficulty taking deep breath or difficulty breathing out
    - Shortness of breath
    - Sleep disturbance, night wakening, or symptoms upon awakening
    - Tiredness
    - Wheezing/heavy breathing/fighting for air; **AND**
- Patient is periodically checked to reassess the need for continued therapy based upon the patient's disease severity and level of asthma control

Chronic idiopathic urticaria (CIU)

- Treatment with Xolair (omalizumab) has resulted in clinical improvement as documented by improvement from baseline using objective clinical evaluation tools such as the 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-Q_2oL); **AND**

- Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q_2oL was recorded within the past 30 days.

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.); **OR**
- Patient had an improvement in at least one (1) of the following response criteria:
  - Reduction in nasal polyp size
  - Reduction in need for systemic corticosteroids
  - Improvement in quality of life
  - Improvement in sense of smell
  - Reduction of impact of comorbidities

Management of Immune Checkpoint Inhibitor-Related Toxicity

- May not be renewed

Systemic Mastocytosis

- Disease response as indicated by improvement in signs and symptoms compared to baseline or a decreased frequency of exacerbations

V. Dosage/Administration [1,11-13]

Indication	Dose
Allergic Asthma	75 to 375 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 tables 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.
Chronic idiopathic urticaria	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. **§§** 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.

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.
Management of Immune Checkpoint Inhibitor-Related Toxicity & Systemic Mastocytosis	150 or 300 mg administered subcutaneously every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight. ****Must ONLY be administered by a health care provider.

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.

Asthma Omalizumab Doses Administered Every 4 Weeks (mg) in patients ≥ 12 years				
Pre-treatment serum IgE (IU/mL)	**Body weight (kg)**			
	30 to 60	**> 60 to 70**	**> 70 to 90**	**> 90 to 150**
≥ 30 to 100	150	150	150	300
> 100 to 200	300	300	300	See the following table.
> 200 to 300	300	See the following table.	See the following table.	See the following table.

Asthma Omalizumab Doses Administered Every 2 Weeks (mg) in patients ≥ 12 years				
Pre-treatment serum IgE (IU/mL)	**Body weight (kg)**			
	30 to 60	**> 60 to 70**	**> 70 to 90**	**> 90 to 150**
> 100 to 200	See previous table.	See previous table.	See previous table.	225
> 200 to 300	See previous table.	225	225	300
> 300 to 400	225	225	300	Do not dose.
> 400 to 500	300	300	375	Do not dose.

> 500 to 600	300	375	Do not dose.	Do not dose.
> 600 to 700	375	Do not dose.	Do not dose.	Do not dose

Asthma Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Patients Who Begin Xolair Between the Ages of 6 to <12 Years										
Pre-treatment IgE (IU/mL)	Dosing Freq. (weeks)	Body Weight (kg)								
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	4	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-900	2	225	225	300	375						
>900-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Do Not Dose

Nasal Polyps Omalizumab Doses Administered Every 2 or 4 Weeks (mg)									
Pre-treatment IgE (IU/mL)	Dosing Freq. (weeks)	Body Weight (kg)							
		>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	4	75	150	150	150	150	150	300	300
>100-200		150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525

>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700		450	600	375	450	450	525		
>700-800	2	300	375	450	450	525	600		
>800-900		300	375	450	525	600			
>900-1000		375	450	525	600	Do Not Dose			
>1000-1100		375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						

VI. Billing Code/Availability Information

HCPCS Code:

- J2357 – Injection, omalizumab, 5 mg; 1 billable unit = 5 mg

NDC:

- Xolair 75 mg single-dose prefilled syringe: 50242-0214-xx
- Xolair 150 mg single-dose prefilled syringe: 50242-0215-xx
- Xolair 150 mg single-use vial powder for injection: 50242-0040-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C94.30	Mast cell leukemia not having achieved remission
C94.31	Mast cell leukemia, in remission
C94.32	Mast cell leukemia, in relapse
C96.20	Malignant mast cell neoplasm, unspecified

ICD-10	ICD-10 Description
C96.21	Aggressive systemic mastocytosis
C96.22	Mast cell sarcoma
C96.29	Other malignant mast cell neoplasm
D47.02	Systemic mastocytosis
J33	Nasal polyp
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J45.40	Moderate persistent asthma, uncomplicated
J45.50	Severe persistent asthma, uncomplicated
L29.8	Other pruritus
L29.9	Pruritus, unspecified
L50.1	Idiopathic urticaria

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

Jurisdiction(s): N (9)	**NCD/LCD Document (s):** A57658
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a57658&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): 6, K	**NCD/LCD Document (s):** A52448
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52448&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp. (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp. (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC