Xolair® (omalizumab)
(Subcutaneous)

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I. Length of Authorization

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Xolair 75 mg single-dose prefilled syringe: 1 syringe every 14 days
- Xolair 150 mg single-dose prefilled syringe: 2 syringes every 14 days
- Xolair 150mg powder for injection: 3 vials every 14 days

B. Max Units (per dose and over time) [Medical Benefit]:

Allergic Asthma
- 90 billable units every 14 days

Chronic idiopathic urticaria
- 60 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab mepolizumab, reslizumab, etc.); AND

Moderate-to-severe persistent allergic asthma †

- Patient must be at least 6 years of age; AND
- Patient has a positive skin test or in vitro reactivity to a perennial aeroallergen; 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:

- 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.)

Chronic idiopathic urticaria (CIU) †

- Patient must be 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:
  - Updosing/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 ciclosporin A

  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).

*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 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):

• 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)**
• fexofenadine • loratadine • desloratadine • cetirizine • levocetirizine • clemastine • diphenhydramine • chlorpheniramine • hydroxyzine • cyproheptadine • brompheniramine • triprolidine • dexchlorpheniramine • carbinoxamine

† FDA-approved indication(s)

IV. Renewal Criteria

- Patient continues to meet the 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 with Xolair (omalizumab) 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 symptoms (e.g., decrease in asthma symptom score), as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
  - 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

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.

V. Dosage/Administration

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
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.

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.

Omalizumab Doses Administered Every 2 Weeks (mg) in patients ≥ 12 years	
	Body weight (kg)

Pre-treatment serum IgE (IU/mL)	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

Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Patients with Asthma 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	Do Not Dose	
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375	Do Not Dose			
>600-700		300	225	225	300	375	Do Not Dose				
>700-900	2	225	225	300	375	Do Not Dose					
>900-1100		225	300	375	Do Not Dose						
>1100-1200		300	300	Do Not Dose							
>1200-1300		300	375	Do Not Dose							

VI. Billing Code/Availability Information

Jcode:
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

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 patient-reported 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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
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) and Local Coverage Determinations (LCDs) 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.

Jurisdiction(s): 5, 8	NCD/LCD Document (s): L34741
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L34741&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): N (9)	NCD/LCD Document (s): L33924
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33924&bc=gAAAAAAAAAAAAA==	

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52448
https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52448&bc=gAAAAAAAAAAAAA==	

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 Corporation (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corporation (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