

Xolair® (omalizumab) (Subcutaneous)

Document Number: IC-0146

Last Review Date: 01/05/2021

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

I. Length of Authorization

Coverage will be provided for six months and may be renewed; 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 150mg 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

Nasal Polyps

- 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 monoclonal antibody (e.g., benralizumab, mepolizumab, reslizumab, etc.); **AND**

Moderate-to-severe persistent allergic asthma † ^{1,2,3,20}

- 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 waking, or symptoms upon awakening, tiredness, wheezing/heavy breathing/fighting for air, etc.)
 - Forced expiratory volume in 1 second (FEV₁)

Chronic idiopathic urticaria (CIU) †^{1,4,5,6,8}

- 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-Q₂₀L); **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-Q2oL).

Nasal Polyps † 1,21

- Patient has bilateral symptomatic sino-nasal polyposis; **AND**
- Patient has failed at least 8 weeks of daily intranasal corticosteroid therapy; **AND**
- Patient does NOT have antrochoanal polyps; **AND**
- Patient does NOT have nasal septal deviation that would occlude at least one nostril; **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

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 ‡ 7,9,11

- 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 FEV₁) >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 FEV₁) <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 Criteria¹

- 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 FEV₁ 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-Q₂₀L); **AND**
- Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q₂₀L was recorded within the past 30 days.

Nasal Polyps

- 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.)

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

| 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. |
| 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. |
| Management of Immune Checkpoint Inhibitor-Related Toxicity & Systemic Mastocytosis | 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. |

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. |

XOLAIR® (omalizumab) Prior Auth Criteria

Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2021, Magellan Rx Management

| | | | | |
|--------------|-----|--------------|--------------|-------------|
| > 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 | 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 | | | | | | | |
| >1100-1200 | | 300 | 300 | | | | | | | | |
| >1200-1300 | | 300 | 375 | | | | | | | | |

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 | | 300 | 375 | 450 | 450 | 525 | 600 | | |
| >800-900 | | 300 | 375 | 450 | 525 | 600 | | | |
| >900-1000 | | 375 | 450 | 525 | 600 | | | Do Not Dose | |
| >1000-1100 | 2 | 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

1. Xolair [package insert]. South San Francisco, CA; Genentech, Inc.; November 2020. Accessed December 2020.
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. Referenced with permission from the NCCN Drugs and Biologics Compendium (NCCN Compendium®) Omalizumab. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2020.
10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Management of Immunotherapy-Related Toxicities 1.2020. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed December 2020.
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Systemic Mastocytosis Version 1.2020. National Comprehensive Cancer Network, 2020. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed December 2020.
12. Carter MC, Robyn JA, Bressler PB, Walker JC, Shapiro GG, Metcalfe DD. Omalizumab for the treatment of unprovoked anaphylaxis in patients with systemic mastocytosis. *J Allergy Clin Immunol*. 2007;119(6):1550-1551.
13. Slapnicar C, Trinkaus M, Hicks L, Vadas P. Efficacy of Omalizumab in Indolent Systemic Mastocytosis. *Case Rep Hematol*. 2019;2019:3787586. Published 2019 Sep 16.
14. Jendoubi, F, Gaudenzio, N, Gallini, A, et al. Omalizumab in the treatment of adult patients with mastocytosis: A systematic review. *Clin Exp Allergy*. 2020; 50: 654– 661.
15. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol*. 2001;108(2):184-190.

16. Solèr M, Matz J, Townley R, et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. *Eur Respir J*. 2001;18(2):254-261.
17. Lanier B, Bridges T, Kulus M, et al. Omalizumab for the treatment of exacerbations in children with inadequately controlled allergic (IgE-mediated) asthma. *J Allergy Clin Immunol*. 2009;124(6):1210-1216.
18. Milgrom H, Berger W, Nayak A, et al. Treatment of childhood asthma with anti-immunoglobulin E antibody (omalizumab). *Pediatrics*. 2001;108(2):E36.
19. Saini SS, Bindslev-Jensen C, Maurer M, et al. Efficacy and safety of omalizumab in patients with chronic idiopathic/spontaneous urticaria who remain symptomatic on H1 antihistamines: a randomized, placebo-controlled study. *J Invest Dermatol*. 2015;135(1):67-75.
20. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. *Eur Respir J* 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
21. Gevaert P, Omachi TA, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. *J Allergy Clin Immunol*. 2020 Sep;146(3):595-605. doi: 10.1016/j.jaci.2020.05.032. Epub 2020 Jun 7.
22. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. *Allergy*. 2019;74(12):2312–2319. doi:10.1111/all.13875.
23. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Omalizumab (A57658). Centers for Medicare & Medicare Services. Updated on 11/22/2019 with effective dates 10/03/2018. Accessed December 2020.
24. National Government Services, Inc. Local Coverage Article: Billing and Coding: Omalizumab (A52448). Centers for Medicare & Medicare Services. Updated on 11/01/2019 with effective dates 11/07/2019. Accessed December 2020.

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 |
| C96.21 | Aggressive systemic mastocytosis |
| C96.22 | Mast cell sarcoma |
| C96.29 | Other malignant mast cell neoplasm |
| D47.02 | Systemic mastocytosis |
| J33 | Nasal polyp |

| ICD-10 | ICD-10 Description |
|--------|--|
| 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 |
| J45.41 | 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 |
| 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/search/article-date-search.aspx?DocID=A57658&bc=gAAAAAAAAAAAAAAAA== | |
| Jurisdiction(s): 6, K | NCD/LCD Document (s): A52448 |
| https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A52448&bc=gAAAAAAAAAAAAAAAA== | |

| 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 |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|--|---|--|
| Jurisdiction | Applicable State/US Territory | Contractor |
| 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. |
| 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 |