

Xolair® (omalizumab) (Subcutaneous)

Document Number: MODA-0146

Last Review Date: 10/03/2023

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, 10/2022, 10/2023

I. Length of Authorization

Coverage will be provided for 6 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/autoinjector: 1 syringe/autoinjector every 14 days
- Xolair 150 mg single-dose prefilled syringe/autoinjector: 4 syringes/autoinjectors every 14 days
- Xolair 150 mg single-dose vial for injection: 4 vials every 14 days
- Xolair 300 mg single-dose prefilled syringe/autoinjector: 2 syringes/autoinjectors every 14 days

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

Allergic Asthma

- 75 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

- Will not be used in combination with another anti-IL4, anti-IL5 or IgG2 lambda monoclonal antibody agents (e.g., benralizumab, mepolizumab, reslizumab, dupilumab, tezepelumab etc.); **AND**

Moderate to Severe Persistent Allergic Asthma †^{1-3,20,25,29}

- 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 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 (FEV₁)

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU) †^{1,4-6,8,28}

- 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), urticaria control test (UCT), angioedema control test (AECT), 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, famotidine, etc.)

Note: renewals will require a documented score from an objective clinical evaluation tool (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL, etc.) recorded within the previous 6 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † 1,22,23, 26-27

- 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**
- 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 use 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, dostarlimab, tremelimumab, nivolumab/relatlimab-rmbw, retifanlimab etc.); **AND**
- Patient has refractory and severe (i.e., grade 3: intense or widespread, constant, limiting self-care activities of daily living or sleep) pruritus; **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):^{2,25}**

- 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):^{2,25}**

- 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}**

First Generation H1

- brompheniramine
- carbinoxamine
- chlorpheniramine
- clemastine
- cyproheptadine
- dexchlorpheniramine
- diphenhydramine
- doxepin
- hydroxyzine
- triprolidine

Second Generation H1

- cetirizine
- desloratadine
- fexofenadine
- levocetirizine
- loratadine

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

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: 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 ^{1-3,20,25}

- Patient must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
- Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
 - Use of systemic corticosteroids
 - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
 - Hospitalizations
 - ER visits
 - Unscheduled visits to healthcare provider; **OR**
- Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU) ^{1,4-6,8,28}

- Treatment 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), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q₂₀L); **AND**
- Provider has current UAS7, AAS, DLQI, AE-QoL, UCT, AECT, or Cu-Q₂₀L recorded within the past 6 months.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) ^{1,22,23, 26-27}

- 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 ^{9,10}

- May not be renewed

Systemic Mastocytosis ^{9,11}

- 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.
Chronic Idiopathic Urticaria/Chronic Spontaneous 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.
Chronic Rhinosinusitis with 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 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 or Autoinjector

The pre-filled syringe or autoinjector 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 criteria below:

- 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 or autoinjector 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. Xolair autoinjectors (all doses) are not intended for use in pediatric patients under 12 years of age.

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	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	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 or autoinjector: 50242-0214-xx
- Xolair 150 mg single-dose prefilled syringe or autoinjector: 50242-0215-xx
- Xolair 150 mg single-dose vial powder for injection: 50242-0040-xx
- Xolair 300 mg single-dose prefilled syringe or autoinjector: 50242-0227-xx

VII. References

1. Xolair [package insert]. South San Francisco, CA; Genentech, Inc.; August 2023. Accessed September 2023.
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. 2022 Update. Available from: <https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf>. Accessed September 2023.
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/GA²LEN/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, 2023. 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 September 2023.

10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Management of Immunotherapy-Related Toxicities 2.2023. National Comprehensive Cancer Network, 2022. 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 September 2023.
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Systemic Mastocytosis Version 4.2023. National Comprehensive Cancer Network, 2023. 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 September 2023.
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. Gandhi NA, Bennett BL, Graham NMH, et al. Targeting key proximal drivers of type 2 inflammation in disease. *Nat Rev Drug Discov*. 2016;15(1):35-50.
24. ASCIA Chronic Spontaneous Urticaria (CSU) Position Paper and Treatment Guidelines; updated July 2020. Available at: <https://www.allergy.org.au/hp/papers/chronic-spontaneous-urticaria-csu-guidelines>.
25. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
26. Fokkens WJ, Viskens AS, Backer V, et. al. EPOS/EUFOREA update on indication and evaluation of Biologics in Chronic Rhinosinusitis with Nasal Polyps 2023. *Rhinology* 2023; 61:194.
27. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol* 2023; 151:386.
28. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. *Allergy*. 2022 Mar;77(3):734-766. doi: 10.1111/all.15090. Epub 2021 Oct 20.
29. Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2023 Update. Available from: <http://www.ginasthma.org/2023-gina-main-report>. Accessed September 2023.
30. National Government Services, Inc. Local Coverage Article: Billing and Coding: Omalizumab (A52448). Centers for Medicare & Medicare Services. Updated on 03/04/2022 with effective dates 03/10/2022. Accessed September 2023.

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
J33.0	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.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): 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