



## **Xolair® (omalizumab)** **(Subcutaneous)**

Document Number: IC-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) [HPCS 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 <sup>1</sup>**

Coverage is provided in the following conditions:

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

#### **Universal Criteria <sup>1</sup>**

- 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:
  - $\geq 30$  IU/mL and  $\leq 700$  IU/mL in patients age  $\geq 12$  years; **OR**
  - $\geq 30$  IU/mL and  $\leq 1300$  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 (FEV<sub>1</sub>)

#### **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-Q<sub>20</sub>L); **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**
- Patient has at least three (3) of the following indicators for biologic treatment:
  - Patient has evidence of type 2 inflammation (e.g., tissue eosinophils  $\geq 10/\text{hpf}$ , blood eosinophils  $\geq 150 \text{ cells}/\mu\text{L}$ , or total IgE  $\geq 100 \text{ IU/mL}$ )
  - Patient has required  $\geq 2$  courses of systemic corticosteroids per year or  $>3$  months of low dose corticosteroids, unless contraindicated
  - 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
  - Mucocoeles; **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 ‡<sup>9,11</sup>

- 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):<sup>2,25</sup>

- 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<sub>1</sub>) >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):<sup>2,25</sup>

- 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<sub>1</sub>) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

#### \*\*H1 Antihistamine Products (not all inclusive)<sup>5,8</sup>

##### 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 Criteria <sup>1</sup>

- 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** <sup>1-3,20,25</sup>

- 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 (FEV<sub>1</sub>)

### **Chronic Idiopathic Urticaria/Chronic Spontaneous Urticaria (CIU/CSU)** <sup>1,4-6,8,28</sup>

- 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-Q2oL); **AND**
- Provider has current UAS7, AAS, DLQI, AE-QoL, UCT, AECT, or Cu-Q2oL recorded within the past 6 months.

### **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** <sup>1,22,23, 26-27</sup>

- 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 <sup>9,10</sup>

- May not be renewed

### Systemic Mastocytosis <sup>9,11</sup>

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

## V. Dosage/Administration <sup>1,11-13</sup>

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. <b>**Must ONLY be administered by a health care provider.</b>

### §§ 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.*

### XOLAIR® (omalizumab) Prior Auth Criteria

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

©2023, Magellan Rx Management

**MagellanRx**  
MANAGEMENT™

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				

#### XOLAIR® (omalizumab) Prior Auth Criteria

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

©2023, Magellan Rx Management

>700-900	2	225	225	300	375				
>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, Bindeslev-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<sup>2</sup>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, 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/GA<sup>2</sup>LEN/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

ICD-10	ICD-10 Description
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):

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

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

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

## PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan (“PCHP”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Community Health Plan  
PO Box 59052  
Minneapolis, MN 55459-0052  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ፡ የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013 ) .

ဟ်သုာ်ဟ်သး- နမာ်ကတိ၊ ကညီ ကိာ်အယံ၊ နမာ် ကိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိံး 1.800.940.5049 (TTY: 763.847.4013).

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013), 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).



## PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist  
PreferredOne Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto:customerservice@preferredone.com)

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 509F, HHH Building  
Washington, D.C. 20201  
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

## Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

បំពេញ: ប្រសិនបើ អ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያገኙበት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (ማስማት ለተሳናቸው: 763.847.4013) .

ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်ခံဘက်သို့လွှဲလိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).