Nucala® (mepolizumab)
(Subcutaneous)

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I. Length of Authorization

- Initial: 6 months for severe eosinophilic asthma and CRSwNP; 12 months for EGPA, HES, and all other indications
- Renewal: 12 months for all indications

II. Dosing Limits

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

Severe Eosinophilic Asthma
- 100 billable units every 28 days

EGPA
- 300 billable units every 28 days

Hypereosinophilic Syndrome
- 300 billable units every 28 days

CRSwNP
- 100 billable units every 28 days

III. Initial Approval Criteria

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

   1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**

B. BOTH of the following:
   1. ONE of the following:
      A. The patient has a diagnosis of severe eosinophilic asthma and ALL of the following:
         1. The patient's diagnosis has been confirmed by ONE of the following:
            A. The patient has a baseline (prior to therapy with the requested agent) blood eosinophil count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
            B. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
            C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **AND**
         2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:
            A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
            B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
            C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**
            D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**
      B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:
         1. The requested agent is FDA labeled or compendia supported for EGPA **AND**
         2. ONE of the following:

A. The patient has a baseline (prior to therapy for the requested indication) blood eosinophilia greater than or equal to 1000 cells/microliter **OR**
B. The patient has a baseline (prior to therapy for the requested indication) blood eosinophil level greater than or equal to 10% eosinophils on white blood cell differential count **AND**

3. The patient has a history or presence of asthma **AND**
4. The patient does NOT have severe disease with organ- or life-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia) **AND**
5. ONE of the following:
   A. BOTH of the following:
      1. The patient is currently treated within the past 90 days with oral corticosteroid (OCS) therapy for at least 4 weeks **AND**
      2. The patient will be using oral corticosteroid (OCS) therapy in combination with the requested agent **OR**
   B. The patient has an intolerance or hypersensitivity to therapy with an oral corticosteroid (OCS) **OR**
   C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **AND**
6. The patient will be using the requested agent for ONE of the following:
   A. Treatment of relapsing or refractory disease **OR**
   B. Treatment for maintenance of disease remission **OR**

C. The patient has a diagnosis of hypereosinophilic syndrome (HES) and ALL of the following:
1. The requested agent is FDA labeled or compendia supported for HES **AND**
2. The patient has had a diagnosis of HES for at least 6 months **AND**
3. The patient's diagnosis of HES was confirmed by BOTH of the following:
   A. ONE of the following:
      1. The patient has a peripheral blood eosinophil count greater than 1000 cells/microliter **OR**

2. The patient has a percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells **OR**
3. The patient has marked deposition of eosinophil granule proteins found **OR**
4. The patient has tissue infiltration by eosinophils that is extensive in the opinion of a pathologist **AND**

B. There has been evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) **AND**

4. The patient does NOT have an identifiable non-hematologic secondary (reactive) cause of HES (e.g., infection [e.g., HIV infection or parasitic helminth infection], allergy/atopy, medications [e.g., drug hypersensitivity], collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma [e.g., non-hematologic malignancy]) **AND**
5. The patient does NOT have FIP1L1-PDGFRA-positive disease **AND**
6. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **AND**
7. ONE of the following:

A. The patient has tried and had an inadequate response to ONE of the following:

1. Oral corticosteroid (OCS) therapy **OR**
2. Hydroxyurea **OR**
3. Interferon-a **OR**
4. Another immunosuppressive agent (e.g., cyclosporine, methotrexate) **OR**

B. The patient has an intolerance or hypersensitivity to therapy with an oral corticosteroid, hydroxyurea, interferon-a, or an immunosuppressive agent (e.g., cyclosporine, methotrexate) used in the treatment of HES **OR**

C. The patient has an FDA labeled contraindication to hydroxyurea, interferon-a, and ALL oral corticosteroids and immunosuppressive agents (e.g., cyclosporine, methotrexate) used in the treatment of HES **OR**

D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:

1. The requested agent is FDA labeled or compendia supported for CRSwNP **AND**
2. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS):
   A. Nasal discharge (rhinorrhea or post-nasal drainage)
   B. Nasal obstruction or congestion
   C. Loss or decreased sense of smell (hyposmia)
   D. Facial pressure or pain **AND**
3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND**
4. The patient's diagnosis was confirmed by ONE of the following:
   A. Anterior rhinoscopy or endoscopy **OR**
   B. Computed tomography (CT) of the sinuses **AND**
5. ONE of the following:
   A. The patient has tried and had an inadequate response to ONE intranasal corticosteroid therapy (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) after at least a 4-week duration of therapy **OR**
   B. The patient has an intolerance or hypersensitivity to ONE intranasal corticosteroid therapy (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) **OR**
   C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **OR**

E. The patient has another FDA labeled indication for the requested agent and route of administration **AND**

2. If the patient has an FDA labeled indication, then ONE of the following:
   A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
   B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has a diagnosis of severe eosinophilic asthma, then ALL of the following:
   A. ONE of the following:

1. The patient is NOT currently treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR**
2. The patient is currently treated with the requested agent AND ONE of the following:
    A. The patient is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days **OR**
    B. The patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR**
3. The patient has an intolerance or hypersensitivity to therapy with an inhaled corticosteroid **OR**
4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND**

B. ONE of the following:
1. The patient is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following:
    A. A long-acting beta-2 agonist (LABA) **OR**
    B. A long-acting muscarinic antagonist (LAMA) **OR**
    C. A leukotriene receptor antagonist (LTRA) **OR**
    D. Theophylline **OR**
2. The patient has an intolerance or hypersensitivity to therapy with a long-acting beta-2 agonist (LABA), a long-acting muscarinic antagonist (LAMA), a leukotriene receptor antagonist (LTRA), or theophylline **OR**
3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND**

C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**

3. If the patient has a diagnosis of hypereosinophilic syndrome (HES), then the patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-a, immunosuppressant) in combination with the requested agent **AND**
4. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then BOTH of the following:
    A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) **AND**
    B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent **AND**

5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
6. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
        1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
        2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**
7. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
8. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

IV. Renewal Criteria

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Medical Drug Review process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
    A. The patient has a diagnosis of severe eosinophilic asthma AND BOTH of the following:
        1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
            A. Increase in percent predicted Forced Expiratory Volume (FEV1) **OR**
            B. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**
            C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**
            D. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND**
        2. The patient is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-

2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **OR**

B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
    1. Remission achieved with the requested agent **OR**
    2. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR**
    3. Decrease in hospitalization due to symptoms of EGPA **OR**
    4. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **OR**

C. The patient has a diagnosis of hypereosinophilic syndrome (HES) AND BOTH of the following:
    1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
        A. Decrease in incidence of HES flares **OR**
        B. Escalation of therapy (due to HES-related worsening of clinical symptoms or increased blood eosinophil counts) has NOT been required **AND**
    2. The patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-a, immunosuppressant) in combination with the requested agent **OR**

D. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND BOTH of the following:
    1. The patient has had clinical benefit with the requested agent **AND**
    2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent **OR**

E. The patient has a diagnosis other than severe eosinophilic asthma, EGPA, HES, or CRSwNP AND has had clinical benefit with the requested agent **AND**

3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**

5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib)

Contraindicated as Concomitant Therapy
Nemluvio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Otulfi (ustekinumab-aauz)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)

V. Dosage/Administration

Indication	Dose
Severe Eosinophilic Asthma	Pediatric Patients Aged 6 to 11 years : 40 mg administered subcutaneously once every 4 weeks Adults and Adolescents Aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	300 mg administered subcutaneously once every 4 weeks as 3 separate 100-mg injections. Administer each injection at least 2 inches apart.
Hypereosinophilic Syndrome (HES)	300 mg administered subcutaneously once every 4 weeks as 3 separate 100-mg injections. Administer each injection at least 2 inches apart.
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	100 mg administered subcutaneously once every 4 weeks.

VI. Billing Code/Availability Information

HCPCS Code:

- J2182 - Injection, mepolizumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Nucala 100 mg/mL lyophilized powder single-dose vial: 00173-0881-xx
- Nucala 100 mg/mL single-dose prefilled autoinjector or syringe (cartons of 1): 00173-0892-xx
- Nucala 40 mg/0.4 mL single-dose prefilled syringe (cartons of 1): 00173-0904-xx

VII. References

1. Nucala [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; March 2023. Accessed August 2024.
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. 2019 Update. Available from: http://www.ginasthma.org. Accessed September 2023.
4. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932. doi: 10.1056/NEJMoa1702079.
5. Hellmich B, Flossmann O, Gross WL, et al. EULAR recommendations for conducting clinical studies and/or clinical trials in systemic vasculitis: focus on antineutrophil cytoplasm antibody-associated vasculitis. Ann Rheum Dis 2007; 66: 605-17.

6. Masi AT, Hunder GG, Lie JT; Michel BA, et al. The American College of Rheumatology 1990 criteria for the classification of Churg-Strauss syndrome (allergic granulomatosis and angiitis). Arthritis Rheum. 1990; 33(8):1094-100 (ISSN: 0004-3591).
7. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373.
8. Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. Ann Rheum Dis. 2016 Sep;75(9):1583-94. doi: 10.1136/annrheumdis-2016-209133.
9. Groh M, Panoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force recommendations for evaluation and management. European Journal of Internal Medicine 26 (2015) 545–553.
10. 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]
11. Roufosse F, Kahn JE, Rothenberg ME, et al. Efficacy and safety of mepolizumab in hypereosinophilic syndrome: a Phase III, randomized, placebo-controlled trial. Journal of Allergy and Clinical Immunology (2020), doi: https://doi.org/10.1016/j.jaci.2020.08.037.
12. 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.
13. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed September 2023.
14. Han JK, Bachert C, Fokkens W, et al; SYNAPSE study investigators. Mepolizumab for chronic rhinosinusitis with nasal polyps (SYNAPSE): a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Respir Med. 2021 Apr 16:S2213-2600(21)00097-7. doi: 10.1016/S2213-2600(21)00097-7.
15. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. *Allergy.* 2019;74:2312–2319. DOI: 10.1111/all.13875.
16. 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.
17. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 Update. Available from: http://www.ginasthma.org. Accessed September 2023.
18. 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.

19. 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.
20. Grayson PC, Ponte C, Suppiah R, et al. 2022 American College of Rheumatology/European Alliance of Associations for Rheumatology Classification Criteria for Eosinophilic Granulomatosis with Polyangiitis. Ann Rheum Dis. 2022 Mar;81(3):309-314. doi: 10.1136/annrheumdis-2021-221794.
21. Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2024 Update. Available from: http://www.ginasthma.org. Accessed August 2024.
22. Chipps BE, Jarjour N, Calhoun WJ, et al. A Comprehensive Analysis of the Stability of Blood Eosinophil Levels. Ann Am Thorac Soc. 2021 Dec; 18(12):1978-1987. doi: 10.1513/AnnalsATS.202010-1249OC.
23. Chung, SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Care Res (Hoboken) 2021; 73:1088.
24. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Forcer on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. 2023 Feb; 151(2):386-398. doi: https://doi.org/10.1016/j.jaci.2022.10.026.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D72.110	Idiopathic hypereosinophilic syndrome [IHES]
D72.111	Lymphocytic Variant Hypereosinophilic Syndrome [LHES]
D72.119	Hypereosinophilic syndrome [HES], unspecified
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J45.50	Severe persistent asthma, uncomplicated
J82.81	Eosinophilic pneumonia, NOS
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified
M30.1	Polyarteritis with lung involvement [Churg-Strauss]

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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