Nucala® (mepolizumab)
(Subcutaneous)

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I. Length of Authorization

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

II. Dosing Limits

A. 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 [1]

Coverage is provided in the following conditions:

Patient is required to meet Site of Service specialty infusion program requirements (refer to the Dean Health Plan Site of Service Policy).

Severe Asthma † [1-3,7,10,12,13,19,21,22]

- Prescribed by, or in consultation with, an allergist, pulmonologist, or immunologist; **AND**
- Patient is at least 6 years of age; **AND**
- Patient has severe***** disease; **AND**
- Patient has asthma with an eosinophilic phenotype indicated by blood eosinophils ≥150 cells/µL; **AND**
- History of ≥ 2 asthma exacerbations requiring treatment with systemic corticosteroids or emergency department visit or hospitalization for treatment of asthma within the past year

despite adherent utilization of either an inhaled corticosteroid (ICS) with one (1) additional asthma controller medication or maximally tolerated inhaled corticosteroid/long-acting beta agonist (ICS/LABA) combination product; **AND**

- Prescriber attests to all the following:
  - Member adherent to controller medications; **AND**
  - Member is a non-smoker or is adherent to an attempt at smoking cessation; **AND**
  - Will not be used in combination with another targeted immunomodulator product used for asthma

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome † Φ [1,4-6,23]

- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a rheumatologist, allergist, pulmonologist, or immunologist; **AND**
- Patient has a confirmed diagnosis of EGPA§ (aka Churg-Strauss Syndrome); **AND**
- Documentation of one of the following:
  - Baseline blood eosinophil count > 1000 cells/µL; OR
  - Baseline blood eosinophil count > 10% of the total leukocyte count; **AND**
- Trial of oral corticosteroid therapy (equivalent to prednisone 7.5 mg/day for a minimum of 4 weeks) was ineffective, contraindicated, or not tolerated; AND
- Trial of one of the following was ineffective, contraindicated, or not tolerated
  - Cyclophosphamide
  - Azathioprine
  - Methotrexate
  - Leflunomide

Hypereosinophilic Syndrome (HES) † Φ [1,11]

- Patient is at least 12 years of age; **AND**
- Prescribed by, or in consultation with, a rheumatologist, allergist, pulmonologist, gastroenterologist, hematologist, or other specialist experienced in the diagnosis and treatment of hypereosinopilic syndromes; **AND**
- Diagnosis of hypereosinophilic syndrome (HES) without clinical features consistent with a myeloid disorder; **AND**
- HES has persisted for at least six (6) months; **AND**
- Blood eosinophils > 1000 cells/µL; **AND**
- ≥ 2 or more HES flares within past 12 months; **AND**
- Trial of corticosteroids was ineffective, not tolerated, or contraindicated; **AND**
- Trial of second-line and/or steroid-sparing agent (such as, but not limited to hydroxyurea or interferon alfa) was ineffective, not tolerated, or contraindicated

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † [1,15,16,18,24]

- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, an allergist, immunologist, or otolaryngologist; **AND**
- Diagnosis of chronic rhinosinusitis with nasal polyposis, lasting at least 12 weeks; **AND**
- Bilateral nasal polyposis confirmed with sinus CT scan; **AND**
- Trial of each of the following was ineffective, contraindicated, or not tolerated
    - Oral corticosteroid
    - Nasal corticosteroid spray; **AND**
- Documentation of moderate to severe symptoms of nasal congestion, blockage, or obstruction (such as loss of smell, rhinorrhea, or facial pain)

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all inclusive):[2,12]**

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- SABA use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV_1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

§Eosinophilic Granulomatosis Polyangiitis (EGPA) defined as all of the following:[4,6]

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute eosinophil count >1000 cells/mm^3
- Two or more of the following criteria:
    - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation
    - Neuropathy
    - Pulmonary infiltrates
    - Sinonasal abnormalities
    - Cardiomyopathy
    - Glomerulonephritis
    - Alveolar hemorrhage
    - Palpable purpura
    - Antineutrophil Cytoplasmic Antibody (ANCA) positivity

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

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- 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: parasitic (helminth) infection, herpes zoster infection, severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, hypotension, urticaria, rash, etc.), etc.; **AND**

Severe Asthma [1-3,7,10]

- Documentation showing positive clinical benefit

Eosinophilic Granulomatosis with Polyangiitis/Churg-Strauss Syndrome [1,5,6]

- Documentation showing positive clinical benefit

Hypereosinophilic Syndrome (HES) [1,11]

- Documentation showing positive clinical benefit

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) † [1,15,18]

- Documentation showing positive clinical benefit

V. Dosage/Administration [1]

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

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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

ICD-10	ICD-10 Description
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