Neighborhood Health Plan OF RHODE ISLAND™
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Nucala® (mepolizumab)
(Subcutaneous)

Effective Date: 01/01/2020
Review Date: 12/18/2019, 12/20/2019, 1/29/2020, 9/9/2020, 11/2/2020, 3/18/2021, 01/05/2022, 1/05/2023, 12/07/23, 01/10/2024, 04/24/2024

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

I. Length of Authorization

Coverage is provided for six months and is eligible for renewal for 12 months.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 100 mg/mL single dose vial for injection: 3 vials every 28 days
- 100 mg/mL single dose prefilled autoinjector or syringe for injection: 3 autoinjectors or syringes every 28 days
- 40mg/0.4ml single-dose prefilled syringe for injection: 1 syringe every 28 days

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

Severe Asthma with an eosinophilic phenotype
- 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. Summary of Evidence

Clinical trials evaluating the efficacy and safety of Nucala have demonstrated its effectiveness in reducing exacerbations and improving lung function in patients with severe asthma. Notably, significant reductions in asthma exacerbation rates, improvement in lung function as measured by FEV1, and enhanced asthma control were observed in patients receiving Nucala compared to placebo or standard of care. Additionally, Nucala has shown a favorable safety profile, with adverse events typically being mild to moderate in severity.

IV. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Universal Criteria [1]

- Must not be used in combination with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenra, Nucala, Xolair, Tezspire); **AND**

Severe Asthma † [1-3,7,10]

- Patient is at least 6 years of age; **AND**
- Patient must have severe***** disease; **AND**
- Nucala is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥300 cells/μL within previous 12 months or ≥150 cells/μL within 6 weeks of dosing OR the patient is dependent on systemic corticosteroids; **AND**
- Patient is adherent to current treatment with both of the following medications at optimized doses:
    - Medium to high-dose inhaled corticosteroids; **AND**
    - An additional controller medication (e.g., long-acting beta agonist, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated; **AND**
- Will not be used for treatment acute bronchospasm or status asthmaticus; **AND**
- Patient must have inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., daily oral corticosteroids for at least 3 days, emergency department or urgent care visits, or hospitalizations) in addition to the regular maintenance therapy defined above; **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_1)

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome † Φ [1,5,6]

- Patient is at least 18 years of age; **AND**
- Nucala is prescribed by, or in consultation with, a pulmonologist, rheumatologist, or allergist/immunologist; **AND**
- Patient has a confirmed diagnosis of EGPA§ (aka Churg-Strauss Syndrome); **AND**

- Patient must have blood eosinophils ≥150 cells/μL within 6 weeks of dosing; **AND**
- Patient has been on stable doses of concomitant oral corticosteroid therapy for at least 4 weeks (i.e., prednisone or prednisolone at a dose of 7.5 mg/day); **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses, etc.)

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

- Patient is at least 12 years of age; **AND**
- Patient has been diagnosed with HES for at least 6 months prior to starting treatment; **AND**
- Patient does NOT have non-hematologic secondary HES (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) or FIP1L1-PDGFRα kinase-positive HES; **AND**
- Patient has a history of 2 or more HES flares within the previous 12 months (e.g., documented HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy); **AND**
- Patient must have blood eosinophils ≥1000 cells/μL within 4 weeks of dosing; **AND**
- Used in combination with stable doses of at least one other HES therapy (e.g., oral corticosteroids, immunosuppressive agents, cytotoxic therapy, etc.)

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

- Patient is at least 18 years of age; **AND**
- Patient has bilateral symptomatic sino-nasal polyposis with symptoms lasting at least 8 weeks; **AND**
- Patient has failed on at least 8 weeks of 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 ≥ 10/hpf, blood eosinophils ≥ 150 cells/μL, or total IgE ≥ 100 IU/mL)
    - Patient has required ≥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

- Mucoceles; **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

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all):**

- 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:

- 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); **Φ** Orphan Drug

V. Renewal Criteria [1-3,5-7,10,11]

- 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

- 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_1)

Eosinophilic Granulomatosis with Polyangiitis/Churg-Strauss Syndrome

- Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced by one or more of the following:
  - Patient is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
  - Decrease in maintenance dose of systemic corticosteroids
  - Improvement in BVAS score compared to baseline
  - Improvement in asthma symptoms or asthma exacerbations
  - Improvement in duration of remission or decrease in the rate of relapses

Hypereosinophilic Syndrome (HES)

- Disease response as indicated by a decrease in HES flares from baseline *(**Note:** An HES flare is defined as worsening of clinical signs and symptoms of HES or increasing eosinophils (on at least 2 occasions), resulting in the need to increase oral corticosteroids or increase/add cytotoxic or immunosuppressive HES therapy).*

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

- 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

VI. Dosage/Administration [1]

Indication	Dose
Severe Asthma with eosinophilic phenotype	Pediatric Patients Aged 6 to 11 years (single dose vial only): 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/Churg-Strauss Syndrome	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.
***Note: Single dose vial must be prepared and administered by a healthcare professional, the auto-injector or prefilled syringe may be self-administered.*	

VII. Billing Code/Availability Information

HCPCS Code:

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

NDC:

- 100 mg/mL single dose vial: 00173-0881-xx
- 100 mg/mL single dose prefilled autoinjector or syringe (cartons of 1): 00173-0892-xx

VIII. References

1. Nucala [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; March 2023. Accessed April 2024.
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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.
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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.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
D72.1	Eosinophilia
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
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)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): 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, 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

Policy Rationale:

Nucala was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Nucala according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.