Nucala® (mepolizumab)
(Subcutaneous)

Document Number: IC-260

Last Review Date: 06/1/2018
Date of Origin: 12/04/2015
Dates Reviewed: 12/2015, 07/2016, 03/2017, 06/2017, 09/2017, 12/2017, 01/2018, 03/2018, 06/2018

I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

– 100 mg single dose vial for injection: 3 vials every 28 days

B. Max Units (per dose and over time) [Medical Benefit]:

Severe Asthma with an eosinophilic phenotype

– 100 billable units every 28 days

EGPA

– 300 billable units every 28 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Must not be used in combination with another monoclonal antibody (e.g., benralizumab omalizumab, reslizumab, etc.); **AND**

Severe Asthma †

- Patient must be at least 12 years of age; **AND**
- Patient must have severe* disease; **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; **AND**
- Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
    - Medium to high-dose inhaled corticosteroids; **AND**

- Two or more exacerbations in the previous year; **OR**
- Require daily oral corticosteroids (in addition to the regular maintenance therapy defined above)

Eosinophilic Granulomatosis with Polyangiitis (EGPA) †

- Patient must be at least 18 years of age; **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.

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all inclusive):**
• 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 of 10% or an absolute 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-labeled indication(s)

IV. Renewal Criteria

- Patient continues to meet the 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, etc.; **AND**
- Treatment has resulted in clinical benefit:

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

- Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced in 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

V. Dosage/Administration

Indication	Dose
Severe Asthma with eosinophilic phenotype	100 mg administered subcutaneously, by a healthcare professional, once every 4 weeks
Eosinophilic Granulomatosis with Polyangiitis	300 mg administered subcutaneously, by a healthcare professional, once every 4 weeks as 3 separate 100-mg injections. Administer each injection at least 2 inches apart.

VI. Billing Code/Availability Information

Jcode:

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

NDC:

- 100 mg single dose vial: 00173-0881-xx

VII. References

1. Nucala [package insert]. Philadelphia, PA; GlaxoSmithKline LLC; December 2017. Accessed April 2018.
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. 2018 Update. Available from: http://www.ginasthma.org. Accessed April 2018.
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)

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82	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) and Local Coverage Determinations (LCDs) 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): 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

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