Policy Title:	Nucala (mepolizumab) (subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/18/2019, 12/20/2019, 1/29/20, 9/9/20		
Revision Date:	12/18/2019, 1/29/20, 9/9/20		

Purpose: To support safe, effective and appropriate use of Nucala (mepolizumab).

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

Policy Statement:

Nucala (mepolizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Nucala (mepolizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

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

Asthma

- Member is 6 years of age or older; AND
- Nucala is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Member has documentation of severe asthma (see Appendix); AND
- Member has documentation of baseline blood eosinophil count of at least 150 cells per microliter within 6 weeks of dosing; AND
- Member is adherent to current treatment with both of the following medications at optimized doses:
    - Inhaled corticosteroid; AND
    - Additional controller medication (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline); AND

- Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations); AND
- Member will use Nucala as add-on maintenance treatment; AND
- Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair).

Eosinophilic granulomatosis with polyangiitis(EPGA)

- Member is 18 years of age or older; AND
- Nucala is prescribed by, or in consultation with, a pulmonologist, rheumatologist or allergist/immunologist; AND
- Patient has a confirmed diagnosis of EGPA (See Appendix); AND
- Member has documentation of a history or the presence of an eosinophil count of ≥150 cells per microliter within 6 weeks of dosing ; AND
- Member 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.)

Continuation of Therapy Criteria:

Asthma

- Member is 6 years of age or older; AND
- Nucala is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
- Member is tolerating treatment; AND
- Documentation of improvement in asthma symptoms or asthma exacerbations as evidenced by a 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); AND
- Member will use Nucala as add-on maintenance treatment; AND
- Member will not use Nucala concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenra, Xolair)

Eosinophilic granulomatosis with polyangiitis

- Member is 18 years of age or older; AND

- Nucala is prescribed by, or in consultation with, a pulmonologist, rheumatologist or allergist/immunologist; AND
- Member is tolerating treatment; AND
- 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

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	**Dose**	**Maximum dose (1 billable unit = *1* mg)**
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, by a healthcare professional, once every 4 weeks	100 billable units every 28 days
Eosinophilic Granulomatosis with Polyangiitis	300 mg administered subcutaneously, by a healthcare professional, once every 4 weeks as 3 separate 100-mg injections	300 billable units every 28 days

Appendix:

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

- Symptoms throughout the day
- Nighttime awakenings, often 7x/week
- Short-acting beta agonist (SABA) use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Eosinophilic granulomatosis with polyangiitis 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

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2182	Injection, mepolizumab, 1 mg

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)