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

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

Scope: Medicaid, Exchange, 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:

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; 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

- 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 has documentation of a history or presence of asthma; AND
- Member has documentation of a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10% ; AND
- Member has at least two of the following disease characteristics of EGPA:
    - Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    - Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
    - Pulmonary infiltrates, non-fixed; sino-nasal abnormality
    - Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    - Glomerulonephritis (hematuria, red cell casts, proteinuria)
    - Alveolar hemorrhage (by bronchoalveolar lavage)
    - Palpable purpura
    - Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3); 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
- Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease

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 asthma control has improved/stabilized on Nucala treatment from baseline as demonstrated by at least one of the following:
    - A reduction in the frequency and/or severity of symptoms and exacerbations (e.g. decrease in hospitalizations, emergency department or urgent care visits); OR
    - A reduction in the daily maintenance oral corticosteroid dose; 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
- Member has beneficial response to treatment with Nucala and is documented by any of the following:
    - A reduction in the frequency of relapses, or
    - A reduction in the daily oral corticosteroid dose, or
    - No active vasculitis

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	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):

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

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)