Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 11/7/2019

Nucala® (mepolizumab)

FDA approval: 11/04/2015
HCPCS: J2182
Benefit: Medical and Pharmacy

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. Diagnosis of severe eosinophilic asthma
      i. Use as add-on maintenance treatment
      ii. FDA approved age
      iii. Documentation of a consult with an allergist/immunologist or pulmonologist prior to initiation of Nucala therapy
      iv. Patient is currently receiving, and will continue to receive standard of care regimen
      v. Severe eosinophilic asthma identified by:
         1. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment OR
         2. Blood eosinophils greater than or equal to 300 cells/microliter in the past 12 months AND
         3. Repeated hospital/ED visits AND
         4. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids in combination with long acting inhaled β2 agonist or leukotriene modifier for at least 3 months fails to maintain adequate control
      vi. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list
      vii. It cannot be used in combination with other biologics for asthma
      viii. Administered by a health care professional (unless requesting the Nucala prefilled syringes or autoinjectors for self-administration)
   b. Diagnosis of eosinophilic granulomatosis with polyangiitis (GPA)
      i. FDA approved age
      ii. Documentation of a consult with an allergist/immunologist or pulmonologist prior to initiation of Nucala therapy
iii. History or presence of asthma
iv. At least 2 of the following criteria that are typical of EGPA:
   1. Histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   2. Neuropathy
   3. Pulmonary infiltrates
   4. Allergic rhinitis and nasal polyps
   5. Cardiomyopathy
   6. Glomerulonephritis
   7. Alveolar hemorrhage
   8. Palpable purpura
   9. Antineutrophil cytoplasmic antibody (ANCA) positivity
v. It cannot be used in combination with other biologics for asthma

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limit: FDA approved dosing
   b. Initial Authorization Period: Up to 1 year
   c. Renewal Criteria:
      i. Patient has not experienced an adverse reaction to Nucala therapy
      ii. Documented clinical improvement. Examples included, but are not limited to:
         1. Reduction in hospitalizations
         2. Reduction in asthma medication use
         3. Reduction in asthma exacerbations
         4. Improvement in pulmonary function tests
   d. Renewal Authorization Period: Up to 1 year

C. Nucala is considered investigational when used for all other conditions, including but not limited to:
   a. Other asthma conditions
   b. Acute bronchospasm
   c. Status asthmaticus
   d. Eosinophilic Oesophagitis
   e. Hypereosinophilic Syndrome
   f. Chronic Obstructive Pulmonary Disease (COPD)

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Therapeutic considerations:

A. FDA approved indication/Diagnosis
   a. For the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
   b. For the treatment of adults with eosinophilic granulomatosis with polyangiitis

*Please refer to most recent prescribing information.
**B. Background Information**

a. **Severe Eosinophilic Asthma**
   i. Mepolizumab would be the first anti-IL5 biological treatment approved for use in this difficult-to-treat population. Its mechanism of action is to bind with high specificity and affinity to human interleukin 5 (IL-5), the key Th2 cytokine responsible for regulation of blood and tissue eosinophils.
   ii. Mepolizumab is a humanized monoclonal antibody (immunoglobulin G [IgG1], kappa, monoclonal antibody [mAb]) that has been developed as an add-on maintenance treatment for patients with severe asthma with eosinophilic inflammation.
   iii. Severe asthma is defined as asthma that requires treatment with high-dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming uncontrolled or that remains uncontrolled despite this therapy.
   iv. Studies in the severe asthma population have shown that more than half of these patients have persistent eosinophilic airway inflammation despite corticosteroid therapy and there is an increasing recognition of different phenotypes, including a severe eosinophilic asthma phenotype.
   v. Guidelines: No guidelines available that includes mepolizumab in the treatment of severe eosinophilic asthma

b. **Eosinophilic Granulomatosis with Polyangiitis (EGPA, formerly Churg-Strauss Syndrome)**
   i. Rare condition affecting 10-15 people per million
   ii. Mean age of diagnosis is 40 years old, and is rare in children, adolescents, and patients over 65
   iii. Antineutrophil cytoplasmic antibodies (ANCA) found in 40-60% of patients, but it is unknown whether ANCAs have a pathogenic role or if this is simply a manifestation of EGPA
   iv. Multisystem disorder characterized by allergic rhinitis, asthma, and prominent peripheral blood eosinophilia
   v. Primarily affects the lungs, followed by the skin, but also involves the cardiovascular, gastrointestinal, renal, and central nervous systems
   vi. Asthma is the cardinal feature of EGPA, which presents, along with allergic rhinitis and nasal polyps, long before vasculitis and the initial EGPA diagnosis
   vii. The next phase of the disease is typically eosinophilia, high levels of eosinophils in the blood, which are 5% or less in healthy patients and at least 10% up to as high as 60% in EGPA patients
   viii. Vasculitis is the third and final phase of symptoms and includes several organs: fever, fatigue, sudden weight loss, muscle and joint pain, rash, numbness/tingling/loss of strength of hands or feet, chest pain or palpitations, shortness of breath, chronic cough, venous thrombotic events, abdominal pain, blood in stool
   ix. Nucala is the first and only treatment available for adults with EGPA

**C. Efficacy**

*Please refer to most recent prescribing information.*

**D. Medication Safety Considerations**

Black Box Warning: No

*Please refer to most recent prescribing information.*
E. Dosing and administration
   a. Dosing:
      i. Severe Eosinophilic Asthma:
         1. 12 years of age and up: 100 mg subcutaneously every 4 weeks
         2. 6 years to 11 years of age: 40 mg every 4 weeks
      ii. Eosinophilic Granulomatosis with Polyangiitis: 300 mg subcutaneously every 4 weeks

*Please refer to most recent prescribing information.

F. How supplied
   a. 100 mg single dose vial for reconstitution
   b. 100 mg/mL single dose autoinjector or pre-filled syringe

References:


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<td>Criteria update to authorization period and FDA approved age</td>
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<td>Updated criteria to account for new self-injectable Nucala formulation</td>
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<td>1.3</td>
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<td>Updated document for new indication of EGPA</td>
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1.1 Effective Date: 02/11/2016 | New Criteria |

1.0 Effective Date: 11/05/2015 | Preliminary Criteria |

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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm).