Nucala (mepolizumab)
Policy Number: C9704-A

CRITERIA EFFECTIVE DATES:

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<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
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<td>10/30/2019</td>
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J CODE

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<td>RxPA</td>
<td>Q4 2019 20191030C9704-A</td>
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PRODUCTS AFFECTED:
Nucala (mepolizumab)

DRUG CLASS:
Interleukin-5 Antagonists (IgG1 kappa)

ROUTE OF ADMINISTRATION:
Subcutaneous

PLACE OF SERVICE:
Specialty Pharmacy
The recommendation is that medications in this policy will be for medical benefit coverage and will be administered in a place of service that is a non-hospital facility based location (i.e., home infusion provider, provider’s office, free-standing ambulatory infusion center)

AVAILABLE DOSAGE FORMS:
Nucala SOLR 100MG, Nucala SOAJ 100MG/ML, Nucala SOSY 100MG/ML

FDA-APPROVED USES:
Add-on maintenance treatment of severe asthma in adults and pediatric patients ≥ 12 years of age with an eosinophilic phenotype.
For the treatment of eosinophilic granulomatosis with polyangiitis in adults
Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

COMPRENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype
Eosinophilic granulomatosis with polyangiitis

REQUIRED MEDICAL INFORMATION:
A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. (a) Documentation of eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil counts: (a) ≥150 cells/microliter at initiation of therapy (within 6 weeks of request) OR (b)> 300 cells/microliter in the prior 12 months
   AND
2. Documentation that member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following: TWO (2) or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months OR Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations OR Asthma worsens upon tapering of oral corticosteroid therapy OR ONE (1) or more asthma-related urgent treatment (such as hospitalization, emergency room visit, unscheduled physician’s office visit) within the previous 12 months OR Mechanical ventilation in the past 12 months OR Poor symptom control indicated by ACQ score consistently greater than 1.5 or ACT score consistently less than 20) OR Forced expiratory volume in 1 second (FEV1) < 80% predicted OR FEV1/forced vital capacity (FVC) < 0.80

AND

3. Symptoms inadequately controlled (as documented in criteria above) after an adherent regimen of at least 3 months of the following COMBINATION THERAPY or labeled contraindication or clinical intolerance to the agent(s): 1) High-dose inhaled corticosteroid (or maximally tolerated dose) AND ONE (1) ADDITIONAL ASTHMA CONTROLLER MEDICATION (Long-acting beta-agonists, Leukotriene Receptor Antagonists, Inhaled long acting muscarinic antagonist, Theophylline )

AND

4. Nucala (mepolizumab) will not be used as monotherapy for asthma or concurrently with other monoclonal antibodies typically used to treat asthma: Xolair (omalizumab), Cinqair (reslizumab), Dupixent (dupilumab) or Fasenra (benralizumab)

B. EOSINOPHILIA GRANULOMATOSIS WITH POLYANGITIS (EGPA):

1. Documented diagnosis of EGPA supported by (i) Blood eosinophil level of at least 10% of leucocytes OR Absolute eosinophil count > 1,000 cells/µL AND (ii) Presence of at any of the following characteristics typical of EGPA: 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 MRI), Glomerulonephritis (hematuria, red cell casts, proteinuria), Alveolar hemorrhage (by bronchoalveolar lavage), Palpable purpura, or Anti-neutrophil cytoplasmic antibody (ANCA) positive

AND

2. Prescriber attests that patient has refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens [at least 3 months of ORAL corticosteroids with or without an immunosuppressant (e.g. cyclophosphamide, azathioprine, methotrexate)] OR has a contraindication or intolerance to oral corticosteroids and immunosuppressants

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of treatment: up to 12 months at a time

QUANTITY:
Severe asthma (eosinophilic phenotype) for add-on maintenance treatment of patients (12 years and older): One vial per 28 days
Eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome): 100 mg single dose vial for injection: 3 vials every 28 days

PRESCRIBER REQUIREMENTS:
All indications: Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma. Submit consultation notes if applicable.

AGE RESTRICTIONS: Severe Asthma, add on maintenance in patients with eosinophilic phenotype: 6 years of age or older, Eosinophilic Granulomatosis with Polyangitis (EPGA): 18 years of age or older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
   1. Adherence to therapy at least 85% of the time as verified by Prescriber and member’s medication fill history (review Rx history for compliance)
   AND
   2. Nucala (mepolizumab) therapy has resulted in clinical improvement as documented by ONE (1) or more of the following from baseline: Improvement in lung function (increase in percent predicted FEV1 or PEF) from pre-treatment baseline, Decreased utilization of rescue medications, Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids), Decreased frequency of unscheduled clinic, urgent care or emergency department visits, Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal waking wheezing, sustained improvement in Asthma Control Test (ACT) scores, OR Reduction use of ICS, leukotriene or beta agonist therapy

B. EOSINOPHILIA GRANULOMATOSIS WITH POLYANGITIS (EGPA):
   1. Adherence to therapy at least 85% of the time as verified by Prescriber and member’s medication fill history (review Rx history for compliance)
   AND
   2. Nucala (mepolizumab) therapy has resulted in clinical improvement of signs and symptoms compared to baseline as evidenced by ONE (1) or more of the following from baseline: Improvement in asthma symptoms or asthma exacerbations, Improvement in duration of remission or decrease in the rate of relapses, Decrease in severity or frequency of EGPA-related symptoms, Decrease in the frequency and/or severity of relapses, Reduction or discontinuation of maintenance doses of systemic corticosteroids and/or immunosuppressant, Decreased blood eosinophil count or inflammatory markers, Improvement in Birmingham Vasculitis Activity Score (BVAS) score compared to baseline or Member is in remission as defined by BVAS score = 0 and a prednisone/prednisolone daily dose of ≤ 7.5 mg

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Nucala (mepolizumab) that are not an FDA-approved indication or not included in this policy are considered experimental/investigational or not a covered benefit of this policy. This subject to change based on research and medical literature, or at the discretion of Molina Healthcare.

OTHER SPECIAL CONSIDERATIONS:

BACKGROUND:
Nucala, an interleukin (IL)-5 antagonist immunoglobulin G (IgG)1k monoclonal antibody, is indicated for add-on maintenance treatment of patients with severe asthma aged ≥ 12 years who have an
eosinophilic phenotype. Nucala is also indicated for treatment of Eosinophilic Granulomatosis with Polyangiitis (EGPA). Limitations of Use: Nucala is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm/status asthmaticus. Nucala is a human IL-5 antagonist; IL-5 is the main cytokine involved in the growth, differentiation, recruitment, activation, and survival of eosinophils. The most important factor in the pathogenesis of asthma is inflammation, which involves multiple mediators and cell types, including eosinophils. By inhibiting the signaling of IL-5, Nucala decreases the production and survival of eosinophils. However, the exact mechanism of action of Nucala in asthma has not been established. Nucala is not indicated for intravenous (IV) use; it should be administered as a 100 mg subcutaneous (SC) injection once every 4 weeks by a healthcare professional.

APPENDIX:

REFERENCES:


