Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky Medicaid

DRUG NAME	Nucala (mepolizumab)
BILLING CODE	Medical: J2182 (1 unit = 1 mg) Pharmacy: Must use valid NDC code
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Office/Home/Outpatient hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 100 units
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Nucala (mepolizumab) is a **non-preferred** product and will only be considered for coverage under the **medical and pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA/Churg-Strauss Syndrome)

For **initial** authorization:

1. Member must be 18 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a pulmonologist, immunologist, allergist, or rheumatologist; AND
3. Member is on glucocorticoid therapy (i.e., stable dose of oral prednisolone or prednisone of 7.5-50 mg/day for at least 4 weeks) and/or on immunosuppressive therapy; AND
4. Member has diagnosis of EGPA for at least 6 months based on the history or presence of asthma plus eosinophilia (> 1000 cells/μL and/or > 10% of leucocytes) and at least **two** of the following additional features of EGPA:
   a) A biopsy showing histopathological evidence of eosinophilic vasculitis, or perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation;
   b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality);
   c) Pulmonary infiltrates, non-fixed;
   d) Sino-nasal abnormality;
   e) Cardiomyopathy (established by echocardiography or magnetic resonance imaging);
   f) Glomerulonephritis (hematuria, red cell casts, proteinuria);
   g) Alveolar hemorrhage (by bronchoalveolar lavage);
   h) Palpable purpura;
   i) Anti-neutrophil cytoplasmic anti-body (ANCA) positive (myeloperoxidase or proteinase); AND
5. Member has a history of relapsing OR refractory disease defined as **one** of the following:
   a) At least one confirmed EGPA relapse (i.e., requiring increase in oral corticosteroids (OCS) dose, initiation/increased dose of immunosuppressive therapy or hospitalization related to EGPA worsening) within the past 2 years while receiving glucocorticoids;
   b) Failure to attain remission (Birmingham Vasculitis Activity Score [BVAS]=0 and OCS dose ≤ 7.5 mg/day prednisolone or equivalent) within the last 6 months following induction treatment with a

standard regimen (i.e., cyclophosphamide, azathioprine, methotrexate, or mycophenolate mofetil, glucocorticoid dose was ≥ 15 mg/day prednisolone or equivalent) administered for at least 3 months;

6. Member does not have infectious disease, parasitic infection, HIV, Hepatitis B or hypersensitivity to monoclonal antibody or biologic therapy AND member was not receiving any of the following:
   a) Oral glucocorticoid dose of > 50 mg/day prednisolone/prednisone or IV or subcutaneous (SC) glucocorticoids in the last 4-weeks;
   b) Omalizumab within 130 days;
   c) Oral or IV cyclophosphamide within 2 weeks;
   d) Rituximab within 12 months;
   e) IV or SC immunoglobulin within 6 months;
   f) Interferon-α within 6 months;
   g) Anti–tumor necrosis factor therapy within 12 weeks;
   h) Anti-CD52 (alemtuzumab) within 6 months; AND
7. Member does not have a history (or suspected history) of alcohol misuse or substance abuse within 2 years.
8. **Dosage allowed:** 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

SEVERE ASTHMA

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a pulmonologist, immunologist or allergist; AND
3. Member has a baseline peripheral blood eosinophil count 150 cells/microliter or greater at initiation of therapy (within past 90 days) or 300 cells/microliter in the past 12 months; AND
4. Member's asthma has been inadequately controlled after 3 months of conventional treatment including **one** of the following:
   a) High-dose inhaled corticosteroids (ICS) and long-acting inhaled beta-2 agonists (LABA);
   b) ICS and leukotriene receptor antagonist (LTRA);
   c) ICS and theophylline; AND
5. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, LTRA, etc.); AND
6. Medication is not used in combination with Cinqair (reslizumab) or Fasenra (benralizumab).
7. **Dosage allowed:** 100 mg by subcutaneous injection once every 4 weeks.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Medication not being used as monotherapy for asthma; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:

a) Decreased frequency of emergency department visits; OR
b) Decreased frequency of hospitalizations due to asthma symptoms; OR
c) Increase in percent predicted FEV1 from pretreatment baseline; OR
d) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
e) Decreased utilization of rescue medications.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Nucala (mepolizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Granulomatosis with polyangiitis (GPA; Wegener's)
- Microscopic polyangiitis (MPA)
- Organ–threatening EGPA (i.e., organ failure due to active vasculitis, creatinine >5.8 g/dL [>513 μmol/L]) within 3 months
- Life–threatening EGPA (severe alveolar hemorrhage or hemoptysis, rapidly progressive glomerulonephritis, severe gastrointestinal involvement, central nervous system involvement or cardiac involvement)

DATE	ACTION/DESCRIPTION
05/18/2017	New policy for Nucala created. Conventional treatment options expanded.
03/16/2018	New indication of Eosinophilic Granulomatosis With Polyangiitis added.

References:

1. Nucala [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; June, 2019.
2. Nucala. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com. Accessed March 2, 2017.
3. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014;7:53–65.
4. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): A multicentre, double-blind, placebo-controlled trial. Lancet. 2012;380(9842):651-659.
5. Pagnoux C. EGPA: early diagnosis is better. Version June 2013. Division of Rheumatology – Vasculitis clinic. Mount Sinai Hospital, Toronto, ON, Canada. Available at: http://www.cssassociation.org/tl_files/pages/news_%26_events/early%20diagnosis%20egpa%205.2013%20final%20pdf.pdf. Accessed on January 26, 2018.
6. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Identifier NCT00287391, A Study to Investigate Mepolizumab in the Treatment of Eosinophilic Granulomatosis With Polyangiitis; 2018 Jan 26. Available at: https://clinicaltrials.gov/ct2/show/NCT02020889?term=mepolizumab&recrs=e&rank=9.
7. Wechsler ME, Akuthota P, Jayne D, et al. EGPA Mepolizumab Study Team. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med. 2017 May 18;376(20):1921-1932. doi: 10.1056/NEJMoa1702079.
8. Matteson EL. Eosinophilic Granulomatosis with Polyangiitis (EGPA/Churg-Strauss Syndrome). Vasculitis Foundation. Available at: https://www.vasculitisfoundation.org/education/forms/eosinophilic-granulomatosis-with-polyangiitis-churg-strauss-syndrome/.

9. Birmingham Vasculitis Activity Score (version 3). Available at: http://golem.ndorms.ox.ac.uk/calculators/bvas.html.
10. Wechsler ME, Akuthota P, Jayne D et al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. N Engl J Med 2017; Supplementary Appendix.

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