CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Nucala (mepolizumab)
BILLING CODE	J2182 (1 unit = 1 mg)
BENEFIT TYPE	Pharmacy and Medical
SITE OF SERVICE ALLOWED	Home/Office/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 **pharmacy** and **medical** 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 the diagnosis of severe asthma, please follow the clinical criteria on the Ohio Department of Medicaid Unified Preferred Drug List.

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.
12/21/2020	Corrected benefit type to pharmacy and medical (policy error). Severe asthma criteria were removed (now included on the UPDL).

References:

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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.

Effective date: 01/01/2021
Revised date: 12/21/2020