

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Nucala (mepolizumab)
BILLING CODE	J2182 (1 unit = 1 mg)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 100 units
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Nucala (mepolizumab) is a **non-preferred** product and will only be considered for coverage under the **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/ $\mu$ L 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  $\leq$ 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  $\geq$ 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- $\alpha$  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 Fasena (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 [ $>513 \mu\text{mol/L}$ ] 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:

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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](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/>.
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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: 09/07/2018

Revised date: 03/16/2018