

## 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.

### 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).
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 diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
05/18/2017	New policy for Nucala created. Conventional treatment options expanded.

References:

1. Nucala [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; 2017. Accessed March 2, 2017.
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.

Effective date: 07/01/2017

Revised date: 05/18/2017