Humana. CareSource™

PHARMACY POLICY STATEMENT
Kentucky 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 **NOT** MEDICALLY NECESSARY	Click Here

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
05/23/2017	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.

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