CareSource

PHARMACY POLICY STATEMENT
Indiana 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	Home/Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see dosage allowed
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.

HYPEREOSINOPHILIC SYNDROME (HES)

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or in consultation with an immunologist, allergist, or hematologist; AND
3. Member has diagnosis of HES; AND
4. Member has a documented blood eosinophil count of >1500 cells/ µL; AND
5. Member has trialed and failed Glucocorticoids for at least one month; AND
6. Member has a history of 2 or more HES flares within the past year defined as worsening of clinical signs and symptoms or increasing eosinophils requiring an escalation in therapy; AND
7. Member does **not** have either of the following:
   a) Identifiable non-hematologic secondary cause (i.e., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy);
   b) FIP1L1-PDGFRα kinase positive HES.
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 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has demonstrated improvement (i.e. reduction of HES flares, reduction in blood eosinophil count).

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

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 in consultation with a pulmonologist, immunologist, allergist, or rheumatologist; AND
3. Member has a confirmed diagnosis of EGPA with a history or presence of asthma and documented eosinophilia (>1500 cells/μL and/or >10% of leucocytes); AND
4. Member has trialed and failed glucocorticoids with or without an immunosuppressant (cyclophosphamide, azathioprine, methotrexate, rituximab) for at least 4 weeks; AND
5. Member does **not** have either of the following:
   a) Diagnosis of GPA or MPA;
   b) Organ-threatening or imminently life-threatening EGPA.
6. **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 6 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has demonstrated improvement (i.e. reduction in relapse rate, oral corticosteroid (OCS) dose, or blood eosinophil count).

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 6 years of age or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist, immunologist or allergist; AND
3. Member has a blood eosinophil count of at least 300 cells/μL or at least 150 cells/μL if taking maintenance oral corticosteroids (OCS); AND
4. Member has at least two documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least one requiring hospitalization, within last year; AND
5. Member's asthma has been inadequately controlled after 3 months of conventional treatment on medium to high doses of inhaled corticosteroids (ICS) and long acting beta 2-agonists (LABA); AND
6. Medication is being used as add-on maintenance treatment to conventional therapies for asthma (i.e. ICS, LABA, etc.); AND
7. Medication is not used in conjunction with any other biologic therapy for asthma.
8. **Dosage allowed:** 100 mg by subcutaneous injection once every 4 weeks for patients aged 12 years and older. 40 mg by subcutaneous injection once every 4 weeks for patients aged 6 to 11 years.

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 hospitalizations due to asthma exacerbations; OR

b) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
c) Decreased utilization of rescue medications or oral corticosteroids.

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.
03/16/2018	New indication of Eosinophilic Granulomatosis With Polyangiitis added.
12/28/2020	New indication of Hypereosinophilic Syndrome added. Severe Asthma: changed from 12 yo or older to 6 yo or older; adjusted eosinophil count; added documented exacerbations; removed ICS + LTRA and ICS + theophylline treatments; removed increase in predicted FEV1 from reauthorization section. EGPA: adjusted eosinophil count; removed the list of additional EGPA features; removed definitions of relapsing and refractory EGPA (BVAS not used in practice); removed exclusion criteria (only applicable in clinical trial setting) and replaced with no GPA, MPA, or life threatening EGPA; removed hx of alcohol/substance abuse; changed initial approval period from 12 months to 6 months.

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