

## PHARMACY POLICY STATEMENT North Carolina Marketplace

<b>DRUG NAME</b>	<b>Nucala (mepolizumab)</b>
BILLING CODE	J2182
BENEFIT TYPE	Medical or Pharmacy
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
STATUS	Prior Authorization Required

Nucala is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) first approved for the treatment of severe asthma in 2015. Since that time, it has been approved for three additional indications - eosinophilic granulomatosis with polyangiitis (EGPA), hypereosinophilic syndrome (HES), and chronic rhinosinusitis with nasal polyps (CRSwNP). All four indications are eosinophilic-driven disease states. Nucala works by blocking IL-5 binding to the alpha chain of the IL-5 receptor complex. This inhibits IL-5 signaling and reduces the production of eosinophils.

Nucala (mepolizumab) will be considered for coverage when the following criteria are met:

### CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP)

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an allergist, immunologist or otorhinolaryngologist (ENT); AND
3. Member has a diagnosis of severe CRSwNP with at least two of the following symptoms for 12 weeks or more:
  - a) Nasal blockage/obstruction/congestion;
  - b) Nasal discharge;
  - c) Facial pain/pressure;
  - d) Reduction in smell;
4. Chart notes must show documentation of bilateral nasal polyps by direct examination, endoscopy, or sinus CT scan; AND
5. Member has symptoms of chronic rhinosinusitis after at least a 4-week trial with an intranasal corticosteroid (e.g., mometasone, fluticasone) in combination with nasal saline irrigation AND ALL of the following:
  - a) Prior sinonasal surgery;
  - b) Systemic corticosteroids (unless not tolerated or contraindicated); AND
6. Member will use in combination with an intranasal corticosteroid (INCS), unless not tolerated or contraindicated; AND
7. Member does not have ANY of the following:
  - a) Nasal polyp removal surgery within the past 6 months.
  - b) Combination use with Xolair or Dupixent;
  - c) Allergic Fungal rhinosinusitis (AFRS)
8. **Dosage allowed/Quantity limit:** 100 mg by subcutaneous injection once every 4 weeks.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided that show the member has demonstrated improvement in signs and symptoms (i.e. reduction in nasal polyp size or nasal obstruction); AND
2. Medication will be used as add-on maintenance therapy in combination with intranasal corticosteroids, unless not tolerated or contraindicated.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## **HYPEREOSINOPHILIC SYNDROME (HES)**

For **initial** authorization:

1. Member is at least 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 a diagnosis of HES; AND
4. Member has a documented blood eosinophil count of > 1500 cells/ $\mu$ L; 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 ANY of the following:
  - a) Identifiable non-hematologic secondary cause (i.e., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy);
  - b) FIP1L1-PDGFR $\alpha$  kinase positive HES.
8. **Dosage allowed/Quantity limit:** 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. Chart notes have been provided that show the member has demonstrated improvement (i.e. reduction of HES flares, reduction in blood eosinophil count).

***If all the above requirements are met, 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/ $\mu$ L 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/Quantity limit:** 300 mg as 3 separate 100-mg injections administered subcutaneously once every 4 weeks.

***If all the above requirements are met, the medication will be approved for 6 months.***

For **reauthorization**:

1. 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 all the above requirements are met, 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/ $\mu$ L or at least 150 cells/ $\mu$ L 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/Quantity limit:** 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 all the above requirements are met, the medication will be approved for 16 weeks.***

For **reauthorization**:

1. 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 all the above requirements are met, the medication will be approved for an additional 12 months.***

**CareSource considers Nucala (mepolizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.**

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.
10/29/2021	New indication of CRSwNP added. Changed to new format.

## References:

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