CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Nucala (mepolizumab)
BILLING CODE	J2182
BENEFIT TYPE	Medical or Pharmacy
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 biding 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
6. Member has had prior sinonasal surgery; AND
7. Member will use Nucala in combination with an intranasal corticosteroid (INCS), unless not tolerated or contraindicated; AND
8. 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)
9. **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/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 ANY 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/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/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/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/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/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.
11/02/2022	CRSwNP: Removed requirement for trial of systemic steroids.

References:

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