Mepolizumab (Nucala®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Nucala is indicated for add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.

   Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus

B. Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
C. Nucala is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause.
D. Nucala is indicated for add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Asthma:
   1. For initial requests:
      i. Chart notes or medical record documentation showing baseline blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. EGPA:
   1. For initial requests:
      i. Chart notes or medical record documentation showing pretreatment blood eosinophil count.

ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

C. HES:
1. For initial requests:
   i. *FIP1L1-PDGFRA* fusion gene test results.
   ii. Chart notes or medical record documentation showing pretreatment blood eosinophil count.
2. For continuation requests:
   i. *FIP1L1-PDGFRA* fusion gene test results.
   ii. Chart notes or medical record documentation supporting improvement in HES control.

D. CRSwNP:
1. For initial requests:
   i. Chart notes or medical record documentation showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., polyps location, size), or Meltzer Clinical Score or endoscopic nasal polyps score (NPS) (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

III. EXCLUSIONS

Coverage will not be provided for treatment of HES for members with any of the following exclusions:
A. HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy).
B. *FIP1L1-PDGFRA* kinase-positive HES.

IV. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
A. Asthma: allergist/immunologist or pulmonologist
B. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist

V. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Dupixent, Cinqair) indicated for asthma in the past year.

2. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   i. Member is 6 years of age or older.
   ii. Member meets either of the following criteria:
      a. Member has a baseline blood eosinophil count of at least 150 cells per microliter
      b. Member is dependent on systemic corticosteroids

iii. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
   a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
   b. One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s).
   c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).

iv. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
   a. High-dose inhaled corticosteroid
   b. Additional controller (i.e., long acting beta$_2$-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

v. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
3. Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. Member has at least two of the following disease characteristics of EGPA:
   i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   iii. Pulmonary infiltrates, non-fixed
   iv. Sino-nasal abnormality
   v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   vii. Alveolar hemorrhage (by bronchoalveolar lavage)
   viii. Palpable purpura
   ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. Member has had at least one relapse (i.e., requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication or has a refractory disease.

C. Hypereosinophilic syndrome (HES)

Authorization of 12 months may be granted for treatment of HES when all of the following criteria are met:

1. Member is 12 years of age or older.
2. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
3. Member will not use the requested medication as monotherapy.
4. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
5. Member has had HES for at least 6 months.
6. Member has experienced at least two HES flares within the past 12 months.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

1. Authorization of 6 months may be granted for adult members who have previously received a biologic drug (e.g., Dupixent, Xolair) indicated for CRSwNP in the past year.

2. Authorization of 6 months may be granted for treatment of CRSwNP when all of the following criteria are met:
   i. Member is 18 years of age or older.
   ii. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
   iii. The member has CRSwNP despite one of the following:
      a. Prior sino-nasal surgery
      b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
   iv. Member has one of the following:
      a. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
      b. Meltzer Clinical Score of 2 or higher in both nostrils
      c. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
   v. Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
      a. Rhinorrhea (anterior/posterior)
      b. Reduction or loss of smell
      c. Facial pain or pressure
   vi. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

VI. CONTINUATION OF THERAPY

A. Asthma

Authorization of 12 months may be granted for continuation of treatment of severe asthma when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorization of 12 months may be granted for continuation of treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has beneficial response to treatment with the requested medication as demonstrated by any of the following:
   i. A reduction in the frequency of relapses
   ii. A reduction or discontinuance of daily oral corticosteroid dose
   iii. No active vasculitis

C. Hypereosinophilic syndrome (HES)

Authorization of 12 months may be granted for continuation of treatment of HES when all of the following criteria are met:

1. Member is 12 years of age or older.

2. Member has experienced a reduction in HES flares since starting treatment with the requested medication.
3. Member will not use the requested medication as monotherapy.

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)
Authorization of 12 months may be granted for continuation of treatment of CRSwNP when all of the following are met:
1. Member is 18 years of age or older.
2. Member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

VII. OTHER

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Nucala (Mepolizumab)	Asthma	Route of Administration: Subcutaneous 6-11 Years 40mg every 4 weeks ≥12 Years 100mg every 4 weeks
Nucala (Mepolizumab)	Chronic Rhinosinusitis With Nasal Polyps (CRSwNP)	Route of Administration: Subcutaneous ≥18 Years 100mg every 4 weeks
Nucala (Mepolizumab)	Eosinophilic Granulomatosis With Polyangiitis (EGPA)	Route of Administration: Subcutaneous ≥18 Years 300mg every 4 weeks as 3 separate 100-mg injections
Nucala (Mepolizumab)	Hypereosinophilic Syndrome (HES)	Route of Administration: Subcutaneous ≥12 Years 300mg every 4 weeks as 3 separate 100-mg injections

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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EFFECTIVE DATE 12/3/2024

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