Nucala (mepolizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Nucala (mepolizumab) drug policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Nucala is indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
2. Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
3. 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.
4. Nucala is indicated for add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
5. Nucala is indicated for add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

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

POLICY

Documentation

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

A. Asthma:
   1. For initial requests:
      a. Member's chart notes or medical record showing pretreatment blood eosinophil count, dependance on systemic corticosteroids if applicable.
      b. 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:
      a. Member's chart notes or medical record showing pretreatment blood eosinophil count
      b. 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 EGPA control.

C. HES:
   1. For initial requests:
      a. FIP1L1-PDGFRA fusion gene test results
      b. Member's chart notes or medical record showing pretreatment blood eosinophil count
   2. For continuation requests: chart notes or medical record documentation supporting improvement in HES control.

D. CRSwNP:
   1. For initial requests:
      a. Member's chart notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyps score (NPS) (where applicable).
      b. Chart notes, medical record documentation, or claims history supporting previous medications tried. 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.

E. Chronic obstructive pulmonary disease (COPD):
   1. For initial requests:
      a. Member's chart or medical record demonstrating inadequate control (e.g., COPD exacerbations and/or hospitalizations)
      b. 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 positive clinical response (reduction of exacerbations or improvement in FEV_1)

Prescriber Specialties

This medication must be prescribed by or in consultation with one of the following:

A. Asthma: allergist/immunologist or pulmonologist
B. CRSwNP: allergist/immunologist or otolaryngologist
C. COPD: pulmonologist

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., Fasenra, Dupixent, Tezspire, Xolair, Cinqair) indicated for asthma.

2. Authorization of **6 months** may be granted for treatment of severe asthma with an eosinophilic phenotype when ALL of the following criteria are met:
   A. Member is 6 years of age or older
   B. Member meets either of the following criteria:
      i. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
      ii. Member is dependent on systemic corticosteroids
   C. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
      iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
   D. Member has inadequate asthma control despite current treatment with both of the following medications at maximally tolerated doses:
      i. Medium-to-high dose inhaled corticosteroid
      ii. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   E. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala
   F. Member will not use Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Tezspire, Xolair)

B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Authorization of **12 months** may be granted for treatment of eosinophilic granulomatosis with polyangiitis 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:
   a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   c. Pulmonary infiltrates, non-fixed
   d. Sino-nasal abnormality
   e. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   f. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   g. Alveolar hemorrhage (by bronchoalveolar lavage)
   h. Palpable purpura
   i. 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 Nucala 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 does not have either of the following:
    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
3. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter
4. Member will not use Nucala as monotherapy
5. Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
6. Member has had HES for at least 6 months
7. Member has experienced at least two HES flares within the past 12 months

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of **6 months** may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent, Xolair, Tezspire) indicated for CRSwNP

Authorization of **6 months** may be granted for treatment of chronic rhinosinusitis with nasal polyps in members 18 years of age or older when ALL of the following criteria are met:

1. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
2. The member has CRSwNP despite one of the following:
    a. Prior sino-nasal surgery; or
    b. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated
3. 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
4. Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior); or
    b. Reduction or loss of smell; or
    c. Facial pain or pressure
5. Member will continue to use a daily intranasal corticosteroid while being treated with Nucala, unless contraindicated or not tolerated.
6. Member will not use Nucala concomitantly with other biologics indicated for chronic rhinosinusitis with nasal polyps (e.g., Dupixent, Xolair, Tezspire)

E. Chronic obstructive pulmonary disease (COPD)

Authorization of **6 months** may be granted for treatment of COPD in members 18 years of age or older when all of the following criteria are met:

1. Member has inadequately controlled COPD as demonstrated by experiencing at least one of the following within the past year:
    a. Two or more moderate exacerbations requiring systemic corticosteroid and/or antibiotic treatment.
    b. One or more severe exacerbation(s) resulting in hospitalization or an emergency medical care visit.
2. Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.

3. Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
4. Member has a baseline blood eosinophil count of at least 300 cells per microliter.
5. COPD remains uncontrolled after at least 3 months of maximally tolerated background controller therapy (LAMA-LABA and inhaled glucocorticoid, unless contraindicated)
6. Member will continue to use background controller therapy (LAMA-LABA and inhaled glucocorticoid, unless contraindicated) in combination with Nucala.
7. Member will not exceed the maximum FDA-approved dose for this indication.

Continuation of Therapy

A. Asthma

Authorization of **12 months** may be granted for continuation of treatment of severe asthma with an eosinophilic phenotype when ALL of the following criteria are met:

1. Nucala is being prescribed by or in consultation with an allergist/immunologist or pulmonologist.
2. Member is 6 years of age or older.
3. Asthma control has improved on Nucala treatment as demonstrated by at least one of the following:
   a. A reduction in the frequency and/or severity of symptoms and exacerbations
   b. A reduction in the daily maintenance oral corticosteroid dose
4. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Nucala
5. Member will not use Nucala concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Tezspire, Xolair)

B. Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Authorization of **12 months** may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis 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 Nucala as demonstrated by any of the following:
   a. A reduction in the frequency of relapses, or
   b. A reduction in the daily oral corticosteroid dose, or
   c. 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 Nucala
3. Member will not use Nucala as monotherapy

D. Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of **12 months** may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis when ALL the following criteria are met:

1. Member is 18 years of age or older
2. Member has achieved or maintained a positive clinical response to Nucala therapy 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

4. Member will not use Nucala concomitantly with other biologics indicated for chronic rhinosinusitis with nasal polyps (e.g., Dupixent, Xolair, Tezspire)

E. Chronic obstructive pulmonary disease

Authorization of **12 months** may be granted for continuation of treatment of COPD in members 18 years of age or older when all of the following criteria are met:

1. Member has achieved and maintained improved COPD control with Nucala therapy as evidenced by at least one of the following:
   a. A reduction in frequency and/or severity of exacerbations
   b. An improvement in lung function (FEV_1)
2. Member will continue to use maintenance COPD treatments (LAMA-LABA and inhaled glucocorticoid, unless contraindicated) in combination with Nucala
3. Member will not exceed the maximum FDA-approved dose for this indication

Nucala is considered **not medically necessary** for members who do not meet the criteria set forth above.

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.

Nucala (mepolizumab) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Quantity Limit
Nucala 100 mg single-dose vial Nucala 100 mg/mL single-dose prefilled safety syringe Nucala 100 mg/mL single-dose prefilled autoinjector Nucala 40mg/0.4mL, single-dose prefilled syringe	Severe asthma: • Age 12 years or older: 100 mg every 28 days • Age 6 to 11 years: 40 mg every 28 days Eosinophilic granulomatosis with polyangiitis (EGPA) or hypereosinophilic syndrome (HES): 300 mg (three 100 mg injections) every 28 days Chronic rhinosinusitis with nasal polyps: 100 mg every 28 days Chronic obstructive pulmonary disease (COPD): 100 mg every 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2182 Injection, Mepolizumab, 1mg

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POLICY HISTORY

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