Reference number(s)
1655-A

Specialty Guideline Management
Nucala

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nucala	mepolizumab

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[1]

- Nucala is indicated for add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
- Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- 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.
- Nucala is indicated for the add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Nucala is indicated for the 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

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

Documentation

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

Asthma

Initial requests

- Chart notes or medical record showing pretreatment blood eosinophil count, dependance on systemic corticosteroids if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests

Chart notes or medical record documentation supporting improvement in asthma control.

EGPA

Initial requests

- Chart notes or medical record showing pretreatment blood eosinophil count or percentage of blood eosinophil level (where applicable).
- 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.

Continuation requests

Chart notes or medical record documentation supporting beneficial response to treatment.

HES

Initial requests

- FIP1L1-PDGFRA fusion gene test results.
- Chart notes or medical record showing pretreatment blood eosinophil count.

Continuation requests

- FIP1L1-PDGFRA fusion gene test results.
- Chart notes or medical record documentation supporting improvement in HES control.

CRSwNP

Initial requests

- Chart notes or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography details (e.g., polyps location, size), Meltzer Clinical Score, or endoscopic nasal polyps score (NPS) (where applicable).
- 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.

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

COPD

Initial requests

- Chart notes or medical record documentation demonstrating classic signs and/or symptoms of COPD (where applicable).
- Chart notes, medical record documentation, or claims history of previous medications tried, including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy (where applicable).
- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication (where applicable).
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year (where applicable).

Continuation requests

Chart notes or medical record documentation supporting positive clinical response.

Exclusions

Coverage will not be provided for treatment of HES for members with any of the following exclusions:

- HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus [HIV] infection, non-hematologic malignancy).
- FIP1L1-PDGFRA kinase-positive HES.

Prescriber Specialties

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

- Asthma: allergist/immunologist or pulmonologist
- Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist

Coverage Criteria

Asthma[1-7,16]

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.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:

- Member is 6 years of age or older.
- Member meets either of the following criteria:
    - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
    - Member is dependent on systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
    - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
    - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s).
    - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
- Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
    - High-dose inhaled corticosteroid.
    - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline).
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)[1,8-11,17]

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Fasenra) indicated for EGPA in the past year.

Authorization of 12 months may be granted for treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

- Member is 18 years of age or older.
- 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%.
- Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
- Member has at least two of the following disease characteristics of EGPA:[8,9]
    - Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    - Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
    - Pulmonary infiltrates, non-fixed
    - Sino-nasal abnormality
    - Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    - Glomerulonephritis (hematuria, red cell casts, proteinuria)
    - Alveolar hemorrhage (by bronchoalveolar lavage)
    - Palpable purpura
    - Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
- 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 refractory disease.

Hypereosinophilic Syndrome (HES)[1,12,13]

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

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

Chronic Rhinosinusitis with Nasal Polyps[1,14,15,18-20]

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) indicated for CRSwNP in the past year.

Authorization of 6 months may be granted for treatment of chronic rhinosinusitis with nasal polyps when all of the following criteria are met:

- Member is 18 years of age or older.
- Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 4 weeks unless contraindicated or not tolerated.
- The member has CRSwNP despite one of the following:
    - Prior sino-nasal surgery.
    - Prior treatment with systemic corticosteroids within the last two years was ineffective, unless contraindicated or not tolerated.
- Member has one of the following:
    - 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.
    - Meltzer Clinical Score of 2 or higher in both nostrils.
    - A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril.
- Member has symptoms of nasal blockage, congestion, or obstruction plus one of the following additional symptoms:
    - Rhinorrhea (anterior/posterior).
    - Reduction or loss of smell.
    - Facial pain or pressure.
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Chronic Obstructive Pulmonary Disease (COPD)[1,21-23]

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Dupixent) indicated for COPD in the past year.

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

- Member is 18 years of age or older.
- 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.
- 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).
- Member has an absolute blood eosinophil count of at least 150 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing either of the following in the last year:

  - At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.
  - One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets either of the following:
  - Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and long-acting beta$_2$-agonist [LABA]).
  - Member is currently receiving a LAMA and LABA, and has a contraindication to ICS.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Continuation of Therapy

Asthma[1-7,16]

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

- Member is 6 years of age or older.
- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
  - A reduction in the frequency and/or severity of symptoms and exacerbations.
  - A reduction in the daily maintenance oral corticosteroid dose.[7]
- Member will continue to use maintenance asthma treatments (i.e., inhaled corticosteroid and additional controller) in combination with the requested medication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)[1,8-11,17]

Authorization of 12 months may be granted for continuation of treatment of eosinophilic granulomatosis with polyangiitis when all of the following criteria are met:

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

Hypereosinophilic Syndrome (HES)[1]

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

- Member is 12 years of age or older.
- Member has experienced a reduction in HES flares since starting treatment with the requested medication.

Chronic Rhinosinusitis with Nasal Polyps[1,14,15]

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

- Member is 18 years of age or older.
- 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).
- Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

Chronic Obstructive Pulmonary Disease (COPD)[1,21-23]

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

- Members is 18 years of age or older.
- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV_1) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

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.

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