Nucala (mepolizumab) for injection, for subcutaneous use

Policy Number: MC/PC 028
Effective Date: July 1, 2026

Instructions for Use

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Related Policies

- N/A

Coverage Rationale

This policy is applicable to Nucala (mepolizumab) for injection, for subcutaneous use only.

Severe Asthma

For initial coverage of Nucala (mepolizumab) injection for severe asthma, the following will be required:

- Diagnosis of severe asthma **and**
- Asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level greater than or equal to 150 cells/microliter **and**
- One of the following:
  - Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids (e.g., prednisone) within the past 12 months **or**
  - Prior asthma-related hospitalization within the past 12 months **and**
- One of the following:
  - Both of the following:
    - Patient is 6 years of age or older but less than 12 years of age **and**
    - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
      - Both of the following:
        - Medium-dose inhaled corticosteroid (ICS) (e.g., greater than 100 – 200 mcg fluticasone propionate equivalent/day)
        - Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) **or**
      - One medium dose combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100mcg/salmeterol 50mcg], Symbicort [budesonide 80mcg/formoterol 4.5mcg] Breo Ellipta [fluticasone furoate 50 mcg/ vilanterol 25 mcg]) **or**

- Both of the following:
  - Patient is 12 years of age or older **and**
  - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
    - Both of the following:
      - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
      - Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) **or**
    - One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500mcg/salmeterol 50mcg], Symbicort [budesonide 160mcg/formoterol 4.5mcg], Breo Ellipta [fluticasone 200mcg/ vilanterol 25mcg]) **and**
- Prescribed by or in consultation with one of the following:
  - Pulmonologist
  - Allergist/Immunologist

For reauthorization coverage of Nucala (mepolizumab) injection for severe asthma, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV_1], decreased use of rescue medications) **and**
- Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications **and**
- Prescribed by or in consultation with one of the following:
  - Pulmonologist
  - Allergist/Immunologist

Chronic obstructive pulmonary disease (COPD)

For initial coverage of Nucala (mepolizumab) injection for chronic obstructive pulmonary disease (COPD), the following will be required:

- Diagnosis of chronic obstructive pulmonary disease (COPD) **and**
- Presence of Type 2 inflammation evidenced by blood eosinophils greater than or equal to 300 cells per microliter at baseline or in the last 12 months **and**
- Patient is receiving one of the following therapies at maximally tolerated doses:
  - Triple therapy (i.e., an inhaled corticosteroid (ICS) [e.g., budesonide], a long-acting muscarinic antagonist (LAMA) [e.g., tiotropium, umeclidinium] and a long-acting beta-2 agonist (LABA) [e.g., salmeterol, arformoterol, formoterol]
  - If ICS are contraindicated, a LAMA and a LABA **and**
- Patient must have post-bronchodilator forced expiratory volume [FEV_1]/forced vital capacity [FVC] ratio less than 0.70 **and**
- Patient has had one of the following within the past 12 months:
  - At least two exacerbations where systemic corticosteroids [intramuscular, intravenous, or oral (e.g., prednisone)] were required at least once
  - COPD-related hospitalization

For reauthorization coverage of Nucala (mepolizumab) injection for chronic obstructive pulmonary disease (COPD), the following will be required:

- Patient demonstrates a positive clinical response to therapy (e.g., improved lung function, a reduction in COPD exacerbations) **and**

- Patient continues to receive one of the following therapies:
    - Triple therapy (i.e., an inhaled corticosteroid (ICS) [e.g., budesonide], a long-acting muscarinic antagonist (LAMA) [e.g., tiotropium, umeclidinium] and a long-acting beta-2 agonist (LABA) [e.g., salmeterol, arformoterol, formoterol]
    - If ICS are contraindicated, a LAMA and a LABA

Chronic rhinosinusitis with nasal polyps (CRSwNP)

For initial coverage of Nucala (mepolizumab) injection for chronic rhinosinusitis with nasal polyps (CRSwNP), the following will be required:

- Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **and**
- Patient is 18 years of age or older
- Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) **and**
- Used in combination with another agent for CRSwNP **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

For reauthorization coverage of Nucala (mepolizumab) injection for chronic rhinosinusitis with nasal polyps (CRSwNP), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal obstruction symptoms via visual analog scale [VAS; 0-10 scale]) **and**
- Used in combination with another agent for CRSwNP **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

For initial coverage of Nucala (mepolizumab) injection for eosinophilic granulomatosis with polyangiitis (EGPA), the following will be required:

- Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) **and**
- Patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy) **and**
- Patient is currently receiving corticosteroid therapy (e.g., prednisolone, prednisone) unless there is a contraindication or intolerance to corticosteroid therapy **and**
- Prescribed by or in consultation with one of the following:
    - Pulmonologist
    - Rheumatologist
    - Allergist/Immunologist

For reauthorization coverage of Nucala (mepolizumab) injection for eosinophilic granulomatosis with polyangiitis (EGPA), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., increase in remission time)

Hypereosinophilic Syndrome (HES)

For initial coverage of Nucala (mepolizumab) injection for hypereosinophilic syndrome (HES), the following will be required:

- Diagnosis of hypereosinophilic syndrome (HES) **and**

- Patient is 12 years of age or older
- Patient has been diagnosed for at least 6 months **and**
- Verification that other non-hematologic secondary causes have been ruled out (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy) **and**
- Patient is Fip1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA)-negative **and**
- Patient has uncontrolled HES defined as both of the following:
    - History of 2 or more flares within the past 12 months
    - Pre-treatment blood eosinophil count greater than or equal to 1000 cells/microliter **and**
- Trial and failure, contraindication, or intolerance to one of the following:
    - Corticosteroid therapy (e.g., prednisone)
    - Cytotoxic/immunosuppressive therapy (e.g., hydroxyurea, cyclosporine, imatinib) **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Hematologist

For reauthorization coverage of Nucala (mepolizumab) injection for hypereosinophilic syndrome (HES), the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in flares, decreased blood eosinophil count, reduction in corticosteroid dose)

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J2182	Injection, mepolizumab, 1 mg

ICD-10 Code	Description
D72.11	Hypereosinophilic Syndrome
J31.0	Chronic rhinitis
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified
J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation

ICD-10 Code	Description
J44.9	Chronic obstructive pulmonary disease, unspecified
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82.81	Chronic eosinophilic pneumonia
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified
M30.1	Polyarteritis with lung involvement [Churg-Strauss]

Background

Respiratory and allergy biologics are a mainstay of treatment for severe asthma; in addition, various agents in this class are also indicated for use in chronic spontaneous urticaria (CSU), eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyposis (CRSwNP), allergic fungal rhinosinusitis, hypereosinophilic syndromes (HES), eosinophilic esophagitis (EoE), IgE-mediated food allergy, chronic obstructive pulmonary disease (COPD), bullous pemphigoid, atopic dermatitis, and prurigo nodularis.

Asthma is a chronic lung disease that inflames and narrows the airways, making it difficult to breathe. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages but most often starts during childhood. In 2022, asthma affected an estimated 22 million adults and 4.5 million children in the United States (U.S.). The exact causes of asthma are unknown. A combination of factors such as genetics, certain respiratory infections during childhood, and contact with airborne allergens can contribute to its development. Most patients with asthma also have allergies (Centers for Disease Control and Prevention [CDC] Web site 2024, National Heart, Lung, and Blood Institute [NHLBI] Web site 2024).

Approximately 17% of patients have difficult-to-treat asthma and 3.7% have severe disease. Difficult-to-treat asthma is asthma that is uncontrolled despite prescribing of medium- or high-dose ICS with a second controller (usually a LABA) or with maintenance OCS, or that requires high-dose treatment to maintain good symptom control and reduce exacerbations. Severe asthma is a subset of difficult-to-treat asthma; it is defined as asthma that is uncontrolled despite adherence with maximal optimized high-dose ICS/LABA treatment and management of contributory factors, or that worsens when high-dose treatment is decreased (GINA 2025).

Chronic rhinosinusitis with nasal polyps (CRSwNP) has a prevalence of approximately 2.7% in adults, and peaks in the sixth decade of life. Symptoms include nasal obstruction, reduced sense of smell, and sleep disturbance, all of which can substantially impact the quality of life. Most cases are idiopathic but may be due to genetic, metabolic, or immunologic causes, resulting in inflammation characterized by eosinophilia and elevated levels of IL-4, IL-5, and interleukin-13 (IL-13) (Hopkins 2019). Common treatment options for CRSwNP include saline irrigation and intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids, surgery, and biologic agents in patients with severe symptoms (Hopkins 2019). Biologic agents that are FDA-approved for CRSwNP include dupilumab, mepolizumab, omalizumab, omalizumab-igec, and tezepelumab-ekko.

COPD is a heterogeneous condition characterized by chronic respiratory symptoms resulting from persistent (often progressive) airflow limitation due to airway and/or alveolar abnormalities. These abnormalities are usually caused by genetic risk factors and/or environmental exposures (such as tobacco smoking and inhalation of toxic particles or gases) that occur over the lifetime of a person with COPD. Airflow limitation is caused by a combination of small airway disease (e.g., obstructive bronchiolitis) and parenchymal destruction (emphysema). The most common symptoms of COPD

include dyspnea, cough, and sputum production (Global Initiative for Chronic Obstructive Lung Disease [GOLD] 2026). In 2023, the age-adjusted prevalence of COPD among adults in the U.S. was 3.8%. At that time, COPD was one of the top 5 causes of death, with 141,733 deaths occurring due to COPD in 2023 (CDC Web site 2025).

Treatment goals in COPD aim to reduce symptoms and the risk of future exacerbations. Choice of therapy depends on a patient's severity of dyspnea and risk of exacerbations, and often includes the use of inhaled bronchodilators (ie, long-acting muscarinic antagonists [LAMAs] or LABAs) and ICSs (GOLD 2026). Biologic agents that are FDA-approved for patients with COPD include dupilumab and mepolizumab. Type 2 inflammation is associated with an increased risk of exacerbations. An estimated 885,000 (0.6% of the U.S. adult population) patients ≥ 40 years of age with COPD in the U.S. are treated with triple therapy; 36% (319,000) of these patients are in a subpopulation who have Type 2 inflammation with blood eosinophils ≥ 300/ μ L and moderate-to-severe uncontrolled COPD.

Eosinophilic Granulomatosis with Polyangiitis (EGPA), previously called Churg-Strauss syndrome, is a systemic necrotizing vasculitis that affects small-to-medium-sized vessels. It is typically associated with eosinophilia and severe asthma (Chung et al 2021, Groh et al 2015, Padmanabhan et al 2019). EGPA is a rare condition with a prevalence of approximately 13 cases per 1 million persons and an annual incidence of approximately 7 new cases per 1 million persons. It has a higher incidence in patients with asthma (Groh et al 2015). Systemic glucocorticoids are the mainstay of treatment for EGPA. For refractory EGPA, the addition of cyclophosphamide, azathioprine, mepolizumab, methotrexate, rituximab, or intravenous immunoglobulins (IVIG) can be considered (Chung et al 2021, Groh et al 2015). In more than 85% of patients with EGPA, remission can be achieved with glucocorticoids with or without an immunosuppressant; however, relapses occur in more than 33% of patients (Pagnoux and Groh 2016).

Hypereosinophilic Syndromes (HES) are disorders characterized by the overproduction of eosinophils, which causes organ damage (Roufosse et al 2025). Treatment for idiopathic HES may include systemic glucocorticoids, imatinib, hydroxyurea, interferon alfa, alemtuzumab, and Janus kinase inhibitors (e.g., tofacitinib and ruxolitinib). Additionally, mepolizumab was FDA-approved for HES in 2020.

Clinical Evidence

Asthma

The safety and efficacy of mepolizumab were evaluated in 3 double-blind, placebo-controlled, multicenter, RCTs in adolescent and adult patients with severe refractory asthma and signs of eosinophilic inflammation. Generally, patients were eligible for enrollment in the trials if they had eosinophils ≥ 150 cells/ μ L in the peripheral blood at screening or ≥ 300 cells/ μ L at some time during the previous year. Patients also were required to be on a high-dose ICS as well as another controller medication (Bel et al 2014, Ortega et al 2014, Pavord et al 2012).

- DREAM was a dose-ranging, 52-week, Phase 2b/3 study (N = 621) that compared annual asthma exacerbation frequency and improvements in clinical symptoms between patients receiving 75 mg, 250 mg, and 750 mg IV mepolizumab and placebo. Mepolizumab decreased clinically significant exacerbation rates across all doses compared to placebo, at a rate of 2.40 per patient per year in the placebo group, 1.24 in the 75 mg mepolizumab group ($p < 0.0001$), 1.46 in the 250 mg mepolizumab group ($p = 0.0005$), and 1.15 in the 750 mg mepolizumab group ($p < 0.0001$). No significant improvements were found for secondary clinical symptom measures, which included change in pre-bronchodilator FEV_1 from baseline, or change in ACQ scores (Pavord et al 2012).
- MENSA was a 32-week Phase 3 trial (N = 576) that compared annual asthma exacerbation frequency and improvements in clinical symptoms between patients receiving SC and IV mepolizumab vs placebo. Patients were selected on the basis of frequent exacerbations, treatment with high doses of ICS, and a defined blood eosinophil count. Both SC and IV mepolizumab significantly decreased clinically significant exacerbation rates compared to placebo, at a rate of 1.74 per patient per year in the placebo group, 0.93 per patient per year in the IV mepolizumab group ($p < 0.001$), and 0.83 per patient per year in the SC mepolizumab group ($p < 0.001$). In both the SC and IV mepolizumab-treated groups, the ACQ scores met thresholds for minimal clinically important change and were significantly improved compared to placebo ($p < 0.001$) (Ortega et al 2014).

- SIRIUS was a 24-week Phase 3 trial (N = 135) that compared OCS requirements between patients receiving SC mepolizumab and placebo. The likelihood of a reduction in the daily oral glucocorticoid dose was 2.39 times higher in the mepolizumab group (95% CI, 1.25 to 4.56; p = 0.008). The median reduction in daily OCS dose was 50% (95% CI, 20 to 75) in the mepolizumab-treated group compared to 0% (95% CI, -20 to 33.3) in the placebo group (p = 0.007) (Bel et al 2014).
- A pharmacokinetic study of SC mepolizumab 40 and 100 mg (for bodyweight < 40 and ≥ 40 kg, respectively) every 4 weeks in 36 children 6 to 11 years of age with severe eosinophilic asthma and ≥ 2 exacerbations in the prior year demonstrated reductions in blood eosinophil count by 89% at week 12 (Gupta et al 2019a). A 52-week safety extension study of 30 children demonstrated no safety or immunogenicity concerns, as well as improvements in blood eosinophil counts and asthma control from baseline (Gupta et al 2019b). Findings of these studies supported FDA approval of mepolizumab for the treatment of severe eosinophilic asthma in children (GlaxoSmithKline 2019).
- A systematic review and meta-analysis compared hospitalization or hospitalization and/or emergency room visit rates in patients with severe eosinophilic asthma treated with mepolizumab or placebo in addition to standard of care for ≥ 24 weeks. Four studies (N = 1388) were eligible for inclusion. Mepolizumab significantly reduced the rate of exacerbations requiring hospitalization (relative rate, 0.49; 95% CI, 0.30 to 0.80; p = 0.004) and hospitalization/emergency room visit (relative rate, 0.49; 95% CI, 0.33 to 0.73; p < 0.001) vs placebo (Yancey et al 2017).

Chronic obstructive pulmonary disease (COPD)

The approval of mepolizumab in patients with COPD was based on the MATINEE and METREX trials, both of which were Phase 3, randomized, placebo-controlled, double-blind, parallel-group trials evaluating the efficacy and safety of mepolizumab in patients with eosinophilic COPD. In both trials, patients were ≥ 40 years of age with a ≥ 1-year COPD diagnosis, had a history of ≥ 2 moderate or ≥ 1 severe exacerbation(s) in the prior year despite ≥ 3 months of triple inhaled therapy (high-dose ICS plus LABA plus LAMA), and a post-bronchodilator FEV_1 between 20% and 80% predicted (Pavord et al 2017, Sciurba et al 2025).

- In MATINEE (N = 804), patients had a blood eosinophil count ≥ 300 cells/µL at screening and ≥ 150 cells/µL in the previous year, and were randomized 1:1 to receive 100 mg of mepolizumab or placebo via SC injection every 4 weeks for 52 to 104 weeks. Results demonstrated that mepolizumab significantly reduced the annualized rate of moderate or severe exacerbations (primary outcome) vs placebo (0.80 vs 1.01 events/year; rate ratio, 0.79; 95% CI, 0.66 to 0.94), as well as the annualized rate of exacerbations leading to emergency visits or hospitalization (0.13 vs 0.20 events/year; rate ratio, 0.65; 95% CI, 0.43 to 0.96). Time to first exacerbation was also longer with mepolizumab (median, 419 vs 321 days; HR, 0.77; 95% CI, 0.64 to 0.93) (Sciurba et al 2025).
- In METREX (N = 837), patients were randomized 1:1 to receive 100 mg of mepolizumab or placebo via SC injection every 4 weeks for 52 weeks, and stratified by eosinophilic (blood eosinophils ≥ 150 cells/mm³ at screening or ≥ 300 cells/mm³ in prior year) or non-eosinophilic type (blood eosinophils < 150 cells/mm³ at screening and no evidence of levels ≥ 300 cells/mm³ in prior year). Results demonstrated that among 462 patients with an eosinophilic phenotype, the mean annual exacerbation rate (primary outcome) was significantly lower with mepolizumab (1.40 events/year) vs placebo (1.71 events/year; rate ratio, 0.82; 95% CI, 0.68 to 0.98). No significant reduction was seen in the overall METREX population (rate ratio, 0.98; 95% CI, 0.85 to 1.12) (Pavord et al 2017).

A meta-analysis of 4 RCTs (N = 1953) evaluated mepolizumab for eosinophilic COPD and determined that mepolizumab reduced the annualized rate of moderate or severe exacerbations (rate ratio, 0.80; 95% CI, 0.73 to 0.89) and prolonged time to first exacerbation (HR, 0.78; 95% CI, 0.69 to 0.88) when compared to placebo (Sinclair De Frías et al 2025).

Chronic rhinosinusitis with nasal polyps (CRSwNP)

SYNAPSE, a 52-week, double-blind, randomized, placebo-controlled, multicenter trial, evaluated the efficacy and safety of mepolizumab in adult patients with CRSwNP. A total of 407 patients with recurrent, refractory, severe, bilateral nasal polyp symptoms despite standard care treatment were enrolled. Patients were randomly assigned to receive 100 mg mepolizumab (n = 206) or placebo (n = 201) every 4 weeks. The total endoscopic nasal polyp score significantly improved from baseline with mepolizumab vs placebo (adjusted difference in medians, -0.73; 95% CI, -1.11 to -0.34; p < 0.0001).

The nasal obstruction visual analogue score (VAS) score during weeks 49 to 52 also significantly improved (adjusted difference in medians, -3.14; 95% CI, -4.09 to -2.18; p < 0.0001) (Han et al 2021).

Eosinophilic Granulomatosis with Polyangiitis (EGPA)
A 52-week, randomized, placebo-controlled, double-blind, parallel-group, multicenter, Phase 3 trial assessed the efficacy and safety of mepolizumab as add-on therapy (to glucocorticoid treatment, with or without immunosuppressive therapy) for patients with relapsing or refractory EGPA (Wechsler et al 2017). A total of 136 patients were randomly assigned to mepolizumab 300 mg every 4 weeks (n = 68) or placebo (n = 68). Results demonstrated the following for the mepolizumab and placebo groups, respectively:

- Percentage of patients with ≥ 24 weeks of accrued remission: 28% vs 3% (OR, 5.91; 95% CI, 2.68 to 13.03; p < 0.001).
- Percentage of patients in remission at both week 36 and week 48: 32% vs 3% (OR, 16.74; 95% CI, 3.61 to 77.56; p < 0.001).
- Annualized relapse rate: 1.14 vs 2.27 (RR, 0.50; 95% CI, 0.36 to 0.70; p < 0.001).
- Percentage of patients able to reduce their daily dose of concomitant prednisone or prednisolone to 4 mg or less (average of weeks 48 to 52): 44% vs 7% (OR, 0.20; 95% CI, 0.09 to 0.41; p < 0.001).

Hypereosinophilic Syndrome (HES)
A 32-week, double-blind, placebo-controlled, multicenter, RCT evaluated the efficacy and safety of mepolizumab in patients ≥ 12 years of age with HES (without an identifiable nonhematologic secondary cause) for at least 6 months (Nucala prescribing information 2025, Roufosse et al 2020). A total of 108 patients were assigned to mepolizumab 300 mg every 4 weeks (n = 54) or placebo (n = 54). Results demonstrated the following for mepolizumab and placebo groups, respectively:

- Proportion of patients with ≥ 1 HES flare or withdrew from the trial: 28% vs 56% (OR, 0.28; 95% CI, 0.12 to 0.64; p = 0.002)
- Adjusted mean rate of HES flares per year: 0.50 vs 1.46 (rate ratio, 0.34; 95% CI, 0.19 to 0.63; p < 0.001)
- Probability of first HES flare by week 32: 26.3% vs 52.7% (hazard ratio [HR], 0.34; 95% CI, 0.18 to 0.67; p = 0.002)

Clinical Guidelines

Asthma
The National Asthma Education and Prevention Program (NAEPP) guideline from the NHLBI states that the initial treatment of asthma should correspond to the appropriate asthma severity category, and it provides a stepwise approach to asthma management. Long-term control medications such as ICSs, long-acting bronchodilators, leukotriene modifiers, cromolyn, and immunomodulators should be taken daily on a long-term basis to achieve and maintain control of persistent asthma. ICSs are the most potent and consistently effective long-term asthma control medication. Quick-relief medications such as SABAs and anticholinergics are used to provide prompt relief of bronchoconstriction and accompanying acute symptoms such as cough, chest tightness, and wheezing. Systemic corticosteroids are important in the treatment of moderate or severe exacerbations because these medications prevent progression of the exacerbation, speed recovery, and prevent relapses (NHLBI 2007). A 2020 focused update of the 2007 NAEPP guideline has provided additional updated recommendations on the use of intermittent ICSs and the use of LAMAs as add-on therapy (Cloutier et al 2020).

The 2025 GINA report also provides a stepwise approach to asthma management (GINA 2025). Treatment recommendations are based on patient age, and stepping down should be considered when asthma symptoms have been well-controlled and lung function has been stable for ≥ 2 to 3 months.

- ICS/beta 2-agonist combination products are recommended for both controller (i.e., maintenance treatment) and reliever use in patients ≥ 6 years of age, while the preferred controller option in patients ≤ 5 years of age consists of low-dose ICS plus as-needed SABA as a reliever.

In patients ≥ 6 years of age diagnosed with severe asthma and uncontrolled on Step 4 treatment phenotyping for Type 2 inflammation into categories such as severe allergic, aspirin-exacerbated, allergic bronchopulmonary aspergillosis,

chronic rhinosinusitis, nasal polyposis, atopic dermatitis, or eosinophilic asthma is recommended. Add-on treatment with a biologic agent should be considered as follows:

- Severe allergic asthma: Anti-IgE treatment with omalizumab is recommended for patients ≥ 6 years of age.
- Severe eosinophilic asthma: Add-on anti-IL-5 therapy is recommended for patients ≥ 6 years of age (mepolizumab), ≥ 12 years of age (benralizumab), or ≥ 18 years of age (reslizumab).
- Severe eosinophilic/Type 2 asthma: Anti-IL4 therapy (dupilumab) is recommended for patients ≥ 6 years of age.
- Adults or adolescents requiring oral corticosteroids for maintenance therapy: Anti-IL4 therapy (dupilumab) is recommended.
- Severe asthma: Anti-TSLP therapy (tezepelumab-ekko) is recommended for patients ≥ 12 years of age.
- Prior to initiation of a biologic agent, several factors should be considered including cost, insurance eligibility criteria, evaluation of predictors of response, delivery route, dosing frequency, and patient preference.

The European Respiratory Society/American Thoracic Society guideline on the management of severe asthma suggests the use of anti-IL-5 therapy as an add-on in adults with severe uncontrolled eosinophilic asthma or severe corticosteroid-dependent asthma. A blood eosinophil count of ≥ 150 cells/µL is suggested as a cut-point to guide initiation of anti-IL-5 therapy in adults with severe asthma and prior exacerbations. A blood eosinophil count of ≥ 260 cells/µL or an exhaled nitric oxide level of 19.5 parts per billion or greater may be used to identify adolescents and adults with severe allergic asthma who are likely to benefit from anti-IgE treatment (Holguin et al 2020).

The American College of Chest Physicians (ACCP) also developed a guideline addressing biologic management in adults with severe asthma. For adults with moderate to severe allergic asthma and ≥ 1 exacerbation per year requiring OCS, the panel recommends treatment with either omalizumab or dupilumab, using individual clinical characteristics to guide selection. For severe, steroid-dependent asthma, the panel recommends either anti-IL-5/IL-5 receptor alpha (IL-R α) therapy or dupilumab and recommends dupilumab over tezepelumab-ekko. For moderate to severe asthma that does not demonstrate a clinical response to omalizumab after 4 to 6 months, the panel recommends switching to either anti-IL-5/IL-5R α therapy or dupilumab. For severe asthma that does not respond to anti-IL-5/IL-5R α therapy after 4 to 6 months, the panel recommends either dupilumab or tezepelumab-ekko, with dupilumab preferred in those who are steroid dependent. For those who do not respond to dupilumab after 4 to 6 months, the panel recommends either anti-IL-5/IL-5R α therapy or tezepelumab-ekko, with anti-IL-5/IL-5R α therapy preferred in steroid-dependent patients. Finally, for those with severe asthma receiving anti-IL-5/IL-5R α therapy who have not demonstrated a clinical response by 4 to 6 months, the panel recommends using a post-treatment FeNO ≥25 ppb to guide switching to dupilumab. All recommendations carry a conditional strength of recommendation and are based primarily on very low-certainty evidence (Oberle et al 2026).

COPD

The 2026 GOLD guidelines state that the initial management strategy for stable COPD should be predominantly based on an assessment of the patient's symptoms and risk of exacerbations; the risk of exacerbations is based on a patient's exacerbation history and severity. Key recommendations from the GOLD guidelines are as follows (GOLD 2026):

- Inhaled bronchodilators are central to symptom management in COPD and are commonly administered on a regular basis to prevent or reduce symptoms. LAMAs and LABAs significantly improve lung function, dyspnea, and health status, and reduce exacerbation rates.
- For initial pharmacologic treatment, recommendations are based on the patient's GOLD group status (ie, Group A, B, or E).
    - Group A: Patients should be offered bronchodilator treatment (either short- or long-acting), based on its effect on breathlessness. If available and affordable, long-acting bronchodilator treatment is preferred except in patients with very occasional dyspnea. The treatment should be continued if symptomatic benefit is documented.
    - Group B: Initial therapy should consist of a LAMA + LABA combination, given there are no issues regarding availability, affordability, and adverse events. In patients for whom this combination is not appropriate, treatment with either a LAMA or LABA is recommended.

    - Group E: The preferred initial choice is a LAMA + LABA combination, given there are no issues regarding availability, affordability, and adverse events. The use of ICS + LABA is not encouraged; if use of an ICS is indicated, ICS + LABA + LAMA is preferred since this combination has been shown to be superior to ICS + LABA. The use of ICS + LABA + LAMA may be considered in patients with a blood eosinophil count ≥ 300 cells/µL. Patients with concomitant asthma should be treated like patients with asthma, requiring use of an ICS.
- Follow-up pharmacological treatment: Subsequent adjustments to maintenance therapy may be to manage dyspnea or exacerbations irrespective of the patient GOLD group, as follows:
    - Dyspnea pathway: For persistent dyspnea, use of 2 long-acting bronchodilators (LAMA + LABA) is recommended in patients receiving bronchodilator monotherapy and experiencing persistent breathlessness or exercise limitation. If the addition of a second long-acting bronchodilator does not improve patient symptoms, the following options may be considered:
        - Switching inhaler devices or molecules
        - Implementing or escalating non-pharmacologic treatment(s)
        - Adding ensifentrine if available
        - Investigating and treating other causes of dyspnea
    - Exacerbation pathway: In patients with persistent exacerbations on bronchodilator monotherapy, escalation to LAMA + LABA (or LAMA + LABA + ICS if blood eosinophil count ≥ 300 cells/µL) is recommended. For patients who develop further exacerbations, additional therapy options include escalation to:
        - A LAMA + LABA + ICS if eosinophil counts are ≥ 100 cells/µL
        - Addition of roflumilast and/or azithromycin to LAMA + LABA if eosinophil counts are < 100 cells/µL
        - Addition of dupilumab (if chronic bronchitis) or mepolizumab (with and without chronic bronchitis) to LAMA + LABA + ICS if eosinophil counts are ≥ 300 cells/µL

Chronic rhinosinusitis with nasal polyps (CRSwNP)

- Treatment of CRSwNP is addressed in guidelines from the American Academy of Otolaryngology-Head and Neck Surgery; AAAAI, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology; the International Forum of Allergy & Rhinology; the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA); and the International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (ICAR-RS) (Orlandi et al 2021, Peters et al 2014, Payne et al 2025, Rank et al 2023).
- Routine treatment recommendations include saline irrigation and/or intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids and surgery in patients with severe or refractory symptoms (Orlandi et al 2021, Peters et al 2014, Payne et al 2025, Rank et al 2023). Biologics rather than no biologics are recommended for patients with CRSwNP, and dupilumab is specifically recommended by ICAR-RS (Orlandi et al 2021, Rank et al 2023). The American Academy of Otolaryngology-Head and Neck Surgery guideline states that biologics (including, but not limited to, monoclonal antibodies such as dupilumab, mepolizumab, or omalizumab) should not be used for the treatment of adults with CRS without polyps (Payne et al 2025).
- In 2023, EUFOREA published an updated expert consensus focused on the use of biologics for CRSwNP. Biologics are indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following criteria: evidence of Type 2 inflammation (biological biomarkers); the need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids) or contraindications to systemic corticosteroids, significant quality-of-life impairment, significant loss of smell, and diagnosis of comorbid asthma. Once eligibility according to the EUFOREA 2023 criteria has been determined, a patient's preference for a surgical or non-surgical approach should be considered if funding within the healthcare system allows. In patients who have never had surgery, 4 of the aforementioned criteria need to be met before a biologic is indicated. Patients with previous sinus surgery plus severe asthma may also qualify for treatment in consultation with their pulmonologist. Lastly, biologics should not be initiated in the following situations: CRSwNP and lack of signs of Type 2 inflammation, cystic fibrosis, unilateral nasal polyps, mucoceles, general contraindications for biological treatments (e.g., immunodeficiencies), and patient-related factors such as noncompliance to therapy (Fokkens et al 2023).

Eosinophilic Granulomatosis with Polyangiitis (EGPA)
In 2023, a European guideline developed by a panel of multidisciplinary experts provided recommendations for the diagnosis and management of EGPA. For remission maintenance in patients with severe EGPA, the panel recommended the use of rituximab, mepolizumab, or traditional disease-modifying therapies in combination with glucocorticoids. In patients with non-severe EGPA, the panel suggested treatment with glucocorticoids, either alone or in combination with mepolizumab. Glucocorticoids should be tapered to the minimum effective dosage to reduce toxicity. Key efficacy trials with benralizumab in patients with EGPA were published after these guidelines; benralizumab is recommended only for consideration in patients with disease refractory to mepolizumab (Emmi et al 2023).

In 2021, a joint guideline from the American College of Rheumatology and Vasculitis Foundation published recommendations for the management of EGPA along with other related conditions (Chung et al 2021). The following relevant conditional recommendations were provided:

- Patients with active, severe EGPA should be treated with cyclophosphamide or rituximab over mepolizumab for remission induction.
- Patients with severe EGPA whose disease has entered remission should be treated with methotrexate, azathioprine, or mycophenolate mofetil over mepolizumab for remission maintenance.
- Patients with EGPA who have experienced relapse with nonsevere disease manifestations (i.e., asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: mepolizumab should be added over switching to another agent.
- Patients with EGPA who have experienced relapse with nonsevere disease manifestations (asthma and/or sinonasal disease) while receiving low-dose GCs and no other therapy: mepolizumab should be added over adding methotrexate, azathioprine, or mycophenolate mofetil.
- Patients with EGPA and high serum IgE levels who have experienced relapse with nonsevere disease manifestations (asthma and/or sinonasal disease) while receiving methotrexate, azathioprine, or mycophenolate mofetil: mepolizumab should be added over adding omalizumab.

Both the EGPA (Churg-Strauss) Consensus Task Force recommendations and the American Society for Apheresis guideline recommend glucocorticoids alone for patients without life- and/or organ-threatening EGPA. For patients with life- and/or organ-threatening EGPA, both glucocorticoids and an immunosuppressant are recommended, as well as maintenance therapy with azathioprine or methotrexate. Guidelines from the American Society for Apheresis recognized mepolizumab as a future treatment option, and the EGPA Consensus Task Force recommendations noted that mepolizumab held promise for this condition based on the pilot studies available at the time of guideline development. IVIG can be considered for refractory EGPA or for treatment during pregnancy (Connelly-Smith et al 2023, Groh et al 2015).

Hypereosinophilic Syndrome (HES)
The World Health Organization (WHO) guidance on eosinophilic disorders has stated that identification of rearranged PDGFRA or PDGFRB is important in the management of eosinophilic disorders as those variants respond to imatinib (Shomali and Gotlib 2021). For patients with idiopathic HES (without imatinib-sensitive variants), corticosteroids are first-line therapy; second-line options include hydroxyurea, interferon-alfa, other cytotoxic chemotherapy agents, and hematopoietic stem cell transplantation. The WHO states that mepolizumab is FDA-approved for idiopathic HES, but other biologic agents are considered investigational.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Nucala is an interleukin-5 (IL-5) antagonist monoclonal antibody (IgG1 kappa) indicated for:

- Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma and with an eosinophilic phenotype.
- Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP).
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- 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.

Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

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Policy History/Revision Information

Date	Summary of Changes
11/16/2023	Approved by OptumRx P&T Committee
05/16/2024	Annual Review. Updated language in coverage rationale section in line with drugs in the same class. Updated references.
05/15/2025	Annual Review. Updated language in coverage rationale section in line with drugs in the same class. Updated references.
6/17/2026	Annual Review. Updated language in coverage rationale section in line with drugs in the same class. Updated references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).