

POLICY NAME	Nucala (mepolizumab)	POLICY #	2470P
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Criteria

Coverage Criteria for Asthma

- ☐ **1.1** Documented diagnosis of eosinophilic phenotype severe asthma with one of the following:
 - Peripheral blood eosinophil count of 150 cells per microliter within the previous 6 weeks
 - Patient is dependent on systemic corticosteroids
- ☐ **1.2** Prescribed by an allergist, immunologist, or pulmonologist
- ☐ **1.3** Age 6 years or older
- ☐ **1.4** Documented concurrent use with one of the following:
 - An inhaled corticosteroid and one additional asthma controller medication (e.g., leukotriene receptor antagonist) with lack of asthma control
 - A maximally tolerated ICS/LABA combination inhaler with lack of asthma control

Coverage Criteria for Eosinophilic Granulomatosis with Polyangiitis (Churg-Strauss)

- ☐ **2.1** Documented diagnosis of eosinophilic granulomatosis with polyangiitis
- ☐ **2.2** Prescribed by an allergist, immunologist, or pulmonologist
- ☐ **2.3** Age 18 years or older
- ☐ **2.4** Documented concurrent daily glucocorticoid therapy

Coverage Criteria for Hypereosinophilic Syndrome (HES)

- ☐ **3.1** Documented diagnosis of hypereosinophilic syndrome for 2: 6 months without an identifiable non- hematologic secondary cause (e.g., drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
- ☐ **3.2** Prescribed by a specialist
- ☐ **3.3** Age 12 years or older
- ☐ **3.4** Documentation that the patient has had HES flares while on stable HES therapy (e.g., chronic or episodic oral corticosteroids, immunosuppressive therapy, or cytotoxic therapy)

Coverage of chronic rhinosinusitis with nasal polyps

- ☐ 4.1 Documented diagnosis of rhinosinusitis with nasal polyps
- ☐ 4.2 Prescribed by an otolaryngologist, allergist, or immunologist
- ☐ 4.3 Age 18 years or older
- ☐ 4.4 Documented failure, intolerance, or contraindication to intranasal glucocorticoids

Coverage of Maintenance Treatment of Chronic Obstructive Pulmonary Disease (COPD)

- ☐ 5.1 Documented inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype with both of the following:
 - Baseline eosinophils of ≥ 150 cell/mcL, or in the previous 12 months eosinophils ≥ 300 cell/mcL
 - COPD with moderate to very severe airflow limitation (post-bronchodilator FEV₁/FVC ratio < 0.7 and post-bronchodilator FEV₁ of 20% to 80% predicted) while on an optimized therapy
- ☐ 5.2 Age 18 years or older
- ☐ 5.3 Documentation to support at least one of the following within the previous 12 months:
 - At least two moderate COPD exacerbations (requiring systemic corticosteroids with or without Statement of the Policy Criteria Purpose of the Policy antibiotics) or
 - At least one severe COPD exacerbation (requiring hospitalization)
- ☐ 5.4 Documented concurrent use with one of the following:
 - Triple therapy (i.e., an inhaled corticosteroid (ICS), a long-acting muscarinic antagonist (LAMA), and a long-acting beta agonist (LABA))
 - If ICS is contraindicated, a LAMA and LABA
- ☐ 5.5 Prescribed by or in consultation with a pulmonologist