

<b>Policy Name:</b>	<b>Nucala (mepolizumab)</b>	<b>Policy #:</b>	<b>2470P</b>
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## Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Nucala.

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Nucala vial (reconstituted for injection) under the specialty medical benefit or Nucala prefilled syringe or autoinjector under the specialty pharmacy benefit when the following criteria have been met.

## Criteria

### 1. 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 (such as prednisone)
- 1.2 Prescribed by an immunologist (immune system doctor), allergist (allergy doctor), or pulmonologist (lung doctor)
- 1.3 Age 6 years or older
- 1.4 Documented use with one of the following:
  - An inhaled corticosteroid (ICS) therapy such as Asmanex, Pulmicort or QVAR AND one additional therapy such as montelukast with lack of asthma control
  - An inhaled corticosteroid/long acting beta2 agonist (ICS/LABA) inhaler such as Symbicort or Dulera with lack of asthma control

### 2. Coverage Criteria for Eosinophilic Granulomatosis with Polyangiitis (EGPA or Churg-Strauss)

- 2.1 Documented diagnosis of eosinophilic granulomatosis with polyangiitis
- 2.2 Prescribed by an immunologist (immune system doctor), allergist (allergy doctor), or pulmonologist (lung doctor)
- 2.3 Age 18 years or older
- 2.4 Documented concurrent daily glucocorticoid therapy such as prednisone

### 3. Coverage Criteria for Hypereosinophilic Syndrome (HES)

- 3.1 Diagnosis of hypereosinophilic syndrome for at least 6 months
- 3.2 Syndrome has no identifiable secondary cause
  - Drug hypersensitivity
  - Parasitic helminth infection
  - HIV infection

- Non-hematologic malignancy
- 3.3 Prescribed by a specialist
- 3.4 Age 12 years or older
- 3.5 Documentation that patient has had HES flares while on HES therapy
- Chronic or episodic corticosteroids, such as prednisone or methylprednisolone
  - Immunosuppressive therapy, such as hydroxyurea or cyclophosphamide
  - Cytotoxic therapy, such as imatinib or vincristine
- 4. Coverage of chronic rhinosinusitis with nasal polyps**
- 4.1 Documented diagnosis of rhinosinusitis with nasal polyps
- 4.2 Prescribed by an otolaryngologist (ear nose and throat doctor), allergist, or immunologist
- 4.3 Age 18 years or older
- 4.4 Documented failure, intolerance, or contraindication to intranasal glucocorticoids

**5. Approval Period**

- 5.1 Initial Approval: 12 months
- 5.2 Reapproval: 12 months with documented evidence of improvement
- For asthma, improvement may be indicated by reduction in frequency of exacerbations, reduced used of controller medications, reduction in asthma symptoms, or increase in FEV1 from pretreatment baseline
  - For EGPA, improvement may be indicated by reduction in symptoms
  - For HES, improvement may be indicated by reduction of symptoms or reduction in the number of flares

<b>CPT Codes</b>	
<b>HCPCS Codes</b>	
J2182	Injection, mepolizumab, 1mg

**References**

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3. Grayson PC, Ponte C, Suppiah R, et al. 2022 American College of Rheumatology/European Alliance of Associations for Rheumatology Classification Criteria for Eosinophilic Granulomatosis With Polyangiitis. *Arthritis Rheumatol.* 2022 Mar;74(3):386-392.
4. Ogbogu PU, Bochner BS, Butterfield JH, et al. Hypereosinophilic syndrome: a multicenter, retrospective analysis of clinical characteristics and response to therapy. *J Allergy Clin Immunol.* 2009;124(6):1319.
5. Roufosse F, Kahn JE, Rothenberg ME, et al. Efficacy and safety of mepolizumab in hypereosinophilic syndrome: A phase III, randomized, placebo-controlled trial. *J Allergy Clin Immunol.* 2020;146(6):1397.
6. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. *J Allergy Clin Immunol.* 2023 Feb;151(2):386-398.

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