| Policy Name: | Nucala (mepolizumab) | Policy#: | 2470P |
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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

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

**2. 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

**3. 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

**4. 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

**5. 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 2: 150 cell/mcL, or in the previous 12 months eosinophils 2: 300 cell/mcL
- COPD with moderated tovery severe airflow limitation (post-bronchodilator FEVl/FVC ration <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

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

**6. Approval Period**

6.1 Initial Approval: 12 months

6.2 Reapproval: 12 months with documented evidence of improvement, as indicated in asthma by reduction in frequency of exacerbations, reduced used of controller medications, reduction in asthma symptoms, or increase in FEVl from pretreatment baseline, as indicated in EGPA by an improvement in symptoms, or as indicated in HES by an improvement in symptoms and/or reduction in the number of flares

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Created Date: 02/03/16
Effective Date: 04/06/16
Posted to Website: 01/01/22
Revision Date: 06/11/25