ALASKA MEDICAID
Prior Authorization Criteria

Interleukin-5 Inhibitors
Nucala®, Cinqair®, Fasenra®

FDA INDICATIONS AND USAGE[1,2,3]

Interleukin-5 (IL-5) inhibitors are indicated as an add-on maintenance treatment for patients with severe asthma, the eosinophilic phenotype. Nucala® is also indicated for the treatment of eosinophilic granulomatosis with polyangiitis and hypereosinophilic syndrome (HES). Interleukin -5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Inhibition of IL-5 reduces the production and survival of eosinophils and inflammation.

APPROVAL CRITERIA

Maintenance Treatment of Severe Asthma[1,2,3,4,5,6,7]

1. Patient is 6 years of age or older for Nucala®, 12 years of age or older for Fasenra® or 18 years of age or older for Cinqair® **AND;**
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist **AND;**
3. Patient has the diagnosis of severe asthma **AND;**
4. The member has one of the following blood eosinophil counts:
   A) For Nucala®:
      a) Blood eosinophil count > 150 cells/mcL with 6 weeks of treatment initiation **OR;**
      b) Blood eosinophil count > 300 cells/mcL in the past 12 months **OR;**
   B) For Fasenra®:
      a) Blood eosinophil count ≥ 150 cells/mcL within 4 weeks of treatment initiation **OR;**
   C) For Cinqair®:
      a) Blood eosinophil count > 400 cells/mcL within 4 weeks of treatment initiation **AND;**
5. Patient has ongoing symptoms of asthma with a minimum 3 month trial of a combination inhaled corticosteroid plus a long acting beta agonist, leukotriene modifier or theophylline, or is intolerant to all of these medications **AND;**
6. Requested medication will be used concurrently with other asthma controller medications.

Eosinophilic Granulomatosis with Polyangiitis [1,8]

1. Request is for Nucala® **AND;**
2. Patient is 18 years of age or older **AND;**
3. Prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist **AND;**
4. Patient diagnosis of eosinophilic granulomatosis with polyangiitis based on the presence of at least four of the following diagnostic criteria:
      a) Asthma
      b) Eosinophilia (>10% eosinophils on the differential leukocyte count)
      c) Mononeuropathy or polyneuropathy
      d) Migratory or transient pulmonary infiltrates on chest x-rays
      e) Paranasal sinus abnormalities
      f) Biopsy containing a blood vessel with extravascular eosinophils
5. Patient has been stable on corticosteroids for at least 4 weeks or the prescriber has indicated clinical inappropriateness of corticosteroid therapy.

Hypereosinophilic Syndrome[1]

1. Request is for Nucala® **AND**;
2. Patient is 12 years of age or older **AND;**
3. Prescribed by or in consultation with an allergist, immunologist, rheumatologist, or pulmonologist **AND;**
4. Patient has the diagnosis of hypereosinophilic syndrome (HES) for ≥6 months without an identifiable non-hematologic secondary cause **AND;**
5. Patient has been stable on corticosteroids for at least 4 weeks or the prescriber has indicated clinical inappropriateness of corticosteroid therapy.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria **OR;**
2. Being used in conjunction with another biologic medication (I.E. Enbrel, Xolair, Remicaide, etc.) **OR;**
3. Being used for relief of acute bronchospasms or status asthmaticus.

CAUTIONS[1,2,3]

- Monitor for hypersensitivity reactions after administration.
- Patient should be monitored for new or worsening eye symptoms.
- Corticosteroids should not be discontinued abruptly upon initiation of therapy.
- Monitor patients for vasculitic rash, worsening pulmonary symptoms, or neuropathies.

DURATION OF APPROVAL

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

QUANTITY LIMITS

- Fasenra® - 30 mg subcutaneously every 28 days for the first 3 doses, and then once every 8 weeks
- Nucala® -100 mg subcutaneously once every 28 days for severe asthma

  -300mg every 28 days for Eosinophilic Granulomatosis with Polyangiitis
- Cinqair®: 3 mg/kg IV once every 28 days

REFERENCES / FOOTNOTES:

1. Nucala (mepolizumab) [prescribing information]. Philadelphia, PA: GlaxoSmithKline, LLC.; September 2020.
2. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2019.

3. Cinqair (reslizumab) [prescribing information]. Frazer, PA: Teva Respiratory, LLC; January 2019.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention. 2019. http://ginasthma.org. Available from the Internet. Accessed March 12, 2020.
5. Pavord ID, Korn S, Howarth P et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicenter, double-blind, placebo-controlled trial. Lancet. 2014; 380: 651-659.
6. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet. 2016 Oct; 388(10056):2128-41.
7. Corren J, Weinstein S, Janka L, et al. Phase 3 study of reslizumab in patients with poorly controlled asthma: effects across a broad range of eosinophil counts. Chest. 2016 Mar;S0012-3692(16)45715-6.
8. Groh, Mathieu, et al. Eosinophilic Granulomatosis With Polyangiitis (Churg-Strauss) (EGPA) Consensus Task Force Recommendations for Evaluation and Management. European Journal of Internal Medicine. 26 (2015): 545-553.