IL-5 ANTAGONISTS
Fasenra (benralizumab) Nucala (mepolizumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Fasenra and Nucala are used with other asthma medications for the maintenance treatment of asthma in patients with an eosinophilic phenotype. Fasenra and Nucala are approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines. Fasenra and Nucala reduce severe asthma attacks by reducing the levels of blood eosinophils- a type of white blood cell that contributes to the development of asthma. Nucala is also used in the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) (1-2).

Regulatory Status
FDA-approved indication:
Fasenra is interleukin-5 antagonist monoclonal antibodies (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma ages 12 years and older, and with an eosinophilic phenotype (2).

Nucala is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for: (1)
   1. Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
   2. The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Limitations of use: (1-2)
- Fasenra is not indicated for treatment of other eosinophilic conditions
- Fasenra and Nucala are not indicated for the relief of acute bronchospasm or status asthmaticus

Subjects enrolled in Nucala trial were required to have at least 1 of the following criteria: blood eosinophil count greater than or equal to 300 cells/mcL in past 12 months, eosinophil count greater than or equal 150 cells/ mcL in the past 90 days or sputum eosinophil count greater than or equal to 3% (1).

In clinical trials herpes zoster have occurred in some patients receiving Fasenra or Nucala and varicella vaccination should be considered if medically appropriate prior to starting therapy (1-2).
Eosinophilic granulomatosis with polyangiitis (EGPA), which was previously called the Churg-Strauss syndrome (CSS) or allergic granulomatosis and angitis, is a multisystem disorder characterized by allergic rhinitis, asthma, and prominent peripheral blood eosinophilia. Peripheral blood eosinophilia (usually 5000 to 9000 eosinophils/microL) is the most characteristic finding, although levels over 1500 cells/microL (or greater than 10 percent of the total leukocyte count) should prompt suspicion for EGPA. The primary therapy EGPA is systemic glucocorticoids. An additional immunosuppressive agent is typically added in patients with more advanced or refractory disease (3).

The safety and efficacy of Fasenra in pediatric patients less than 12 years of age have not been established. The safety and efficacy of Nucala in pediatric patients with severe asthma younger than 6 years of age have not been established. The safety and efficacy in pediatric patients less than 18 years of age with EGPA have not been established (1-2).

**Summary**

Fasenra and Nucala are used with other asthma medications for the maintenance treatment of asthma in patients with an eosinophilic phenotype. Fasenra and Nucala have been shown to decrease the incidence of asthma exacerbations in patients with severe asthma whose symptoms are inadequately controlled with inhaled corticosteroids. Nucala is also used in the treatment of eosinophilic granulomatosis with polyangiitis (EGPA). Fasenra and Nucala are not indicated for the relief of acute bronchospasm or status asthmaticus (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Fasenra and Nucala while maintaining optimal therapeutic outcomes.

**References**