BlueCross BlueShield Federal Employee Program

IL-5 ANTAGONISTS

Fasenra (benralizumab) Nucala (mepolizumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Fasenra (benralizumab) and Nucala (mepolizumab) are used in combination 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. Fasenra and Nucala are also used for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA). Nucala is also used in the treatment of certain eosinophilic conditions and hypereosinophilic syndrome (HES), chronic rhinosinusitis with nasal polyps (CRSwNP), and chronic obstructive pulmonary disease (COPD) (1-2).

Regulatory Status

FDA-approved indications:

Fasenra is interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated for: (2)

1. Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype
2. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

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. Add-on maintenance treatment of adult patients 18 years and older with chronic rhinosinusitis with nasal polyps (CRSwNP) with inadequate response to nasal corticosteroids
3. Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype
4. The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)
5. The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) for ≥ 6 months without an identifiable non-hematologic secondary cause

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Limitations of Use: (1-2)

- Fasenra and Nucala are not indicated for the relief of acute bronchospasm or status asthmaticus

Subjects enrolled in Nucala trial for severe asthma 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 to 150 cells/mcL in the past 6 weeks or sputum eosinophil count greater than or equal to 3% (1).

In clinical trials herpes zoster have occurred in some patients receiving Nucala and varicella or herpes zoster 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 angiitis, is a multisystem disorder characterized by allergic rhinitis, asthma, and prominent peripheral blood eosinophilia. Peripheral blood eosinophilia (usually 5000 to 9000 eosinophils/mcL) is the most characteristic finding, although levels over 1500 cells/mcL (or greater than 10 percent of the total leukocyte count) should prompt suspicion for EGPA. The primary therapy for EGPA is systemic glucocorticoids. An additional immunosuppressive agent is typically added in patients with more advanced or refractory disease (3).

FEP adherence is defined as ≥ 50% utilization within the last 180 days.

Subjects enrolled in Nucala trial for HES had experienced at least 2 HES flares within the past 12 months and a blood eosinophil count of 1,000 cells/mcL or higher during screening. Patients must have been on stable HES therapy for the 4 weeks prior to randomization (1).

The safety and effectiveness of Fasenra in pediatric patients less than 6 years of age with severe asthma have not been established. The safety and effectiveness of Fasenra in pediatric patients less than 18 years of age with EGPA have not been established (2).

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The safety and effectiveness of Nucala in pediatric patients less than 18 years of age with EGPA, CRSwNP, and COPD have not been established. The safety and effectiveness of Nucala in pediatric patients less than 12 years of age with HES have not been established. The safety and effectiveness of Nucala in pediatric patients less than 6 years of age with severe asthma have not been established (1).

Summary

Fasenra (benralizumab) and Nucala (mepolizumab) are used in combination 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. Fasenra and Nucala are also used for the treatment of eosinophilic granulomatosis with polyangiitis (EGPA). Nucala is also used in the treatment of certain eosinophilic conditions and hypereosinophilic syndrome (HES), chronic rhinosinusitis with nasal polyps (CRSwNP), and chronic obstructive pulmonary disease (COPD). 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

1. Nucala [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; May 2025.
2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
3. Gioffredi A, Maritati F, et al. Eosinophilic Granulomatosis with Polyangiitis: An Overview. Front Immunol. 2014; 5: 549.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available from www.ginasthma.org.