benralizumab (Fasenra Pen™)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO174

Description

Benralizumab (Fasenra Pen) is a subcutaneously administered monoclonal antibody (IgG1, kappa) that antagonizes IL-5 signaling for the indication of severe eosinophilic asthma (SEA).

Length of Authorization

- Initial: Six months
- Renewal: Six months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
benralizumab (Fasenra)	30 mg/mL autoinjector	Severe eosinophilic asthma	Loading: 1 autoinjector/28 days for 3 doses Maintenance: 1 autoinjector/56 days
Provider Administered Agents*			
benralizumab (Fasenra)	30 mg/mL Syringe	Severe eosinophilic asthma	Loading: 1 autoinjector/28 days for 3 doses Maintenance: 1 autoinjector/56 days

****Medical drug that requires administration by a healthcare professional and is not available for self-administration by the member, considered one of the excluded classes under the prescription benefit.***

Initial Evaluation

I. Benralizumab (Fasenra Pen) may be considered medically necessary when the following criteria below are met:
   A. Must not be used in combination with another monoclonal antibody (e.g., mepolizumab omalizumab, reslizumab, etc.); **AND**
   B. A diagnosis of **Severe Eosinophilic Asthma (SEA); AND**
      1. Member is 12 years of age or older; **AND**
      2. The member has severe asthma as defined by any **one** of the following:
         i. Symptoms throughout the day
         ii. Nighttime awakenings, often 7 times per week

iii. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
iv. Extremely limited normal activities
v. Lung function (percent predicted FEV_1) < 60%
vi. Exacerbations requiring oral systemic corticosteroids are more frequent and intense relative to moderate asthma; **AND**

3. The member must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within 6 weeks of dosing; **AND**
4. Must be used for add-on maintenance treatment in members regularly receiving **BOTH** of the following:
   i. Medium to high-dose inhaled corticosteroids; **AND**
   ii. An additional controller medication (e.g., long-acting beta agonist, etc.); **AND**
5. Members must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above).

II. Benralizumab (Fasenra) is considered investigational when used for all other conditions, including but not limited to:
   A. Non-severe, non-eosinophilic phenotype asthma
   B. Atopic dermatitis
   C. Eosinophilic gastritis
   D. Exercise-induced asthma
   E. Chronic obstructive pulmonary disease (COPD)
   F. Hypereosinophilic syndrome

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. Member has exhibited improvement or stability in asthma symptoms or asthma exacerbations as evidenced by decrease in **one** or more of the following:
   A. Use of systemic corticosteroids
   B. Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days

C. Hospitalizations
D. Emergency department (ED) visits
E. Unscheduled visits to healthcare provider; **OR**

IV. Member has exhibited improvement from baseline in forced expiratory volume in 1 second (FEV_1)

Supporting Evidence

I. Benralizumab (Fasenra Pen) is indicated as an add-on maintenance treatment for patients 12 years and older with a diagnosis of severe eosinophilic asthma (SEA). It is now available for self-administration via an autoinjector based off one phase III and one phase I trial that was conducted with the primary objective of usability and pharmacokinetic (PK) exposure. These trials demonstrated that the safety and tolerability of benralizumab (Fasenra Pen) was consistent with the established profile of the medication.

II. The provider administered, benralizumab (Fasenra) was FDA approved in the setting of severe eosinophilic asthma was evaluated in one 52-week dose ranging exacerbation trial; and three confirmatory randomized, double-blind trials, and one 12-week lung function trial.

- The 52- week dose ranging exacerbation trial was a phase 2 randomized, double-blind, placebo controlled trial. Benralizumab (Fasenra) was administered every 4 weeks for 3 doses followed by every 8 weeks thereafter. In the benralizumab (Fasenra) treatment arm, there was a decrease in annual exacerbation rate with 2, 20, and 100 mg (-12% [80% CI: -51, 18), -34% [80% CI: 6, 54], and -29% [80% CI: 10, 44], respectively).
- The two confirmatory trials were 48 and 52 weeks in duration. The primary outcome was rate of asthma exacerbations in patients with baseline eosinophil counts of ≥300 cells/µL taking both high-dose ICS and LABA. Rates of exacerbation per year in the benralizumab (Fascenra) arm of both trials was 0.74 and 0.73 compared to 1.52 and 1.01 with placebo (Rate Ratio [95% CI: 0.37, 0.64], [95% CI: 0.54, 0.95], respectively).
- The third confirmatory trial was 28 weeks in duration and evaluated the effects of benralizumab (Fascenra) on reducing the use of maintenance oral corticosteroids (OCS). The primary endpoint was percent reduction from baseline of OCS use during weeks 24 to 28. The median percent reduction from baseline in the benralizumab (Fascenra) arm was 75% compared to 25% in placebo (95% CI: 60, 88).
- The 12-week lung function trial measured lung function by the change from baseline FEV_1 at week 12. The benralizumab (Fascenra) arm showed an increase of 0.057 liters compared to -0.016 liters in placebo (p=0.040)

Investigational or Not Medically Necessary Uses

I. Benralizumab (Fasenra) would be considered investigational when used for any of the following indications due to lack of studies:
   A. Non-severe, non-eosinophilic phenotype asthma
   B. Atopic dermatitis
   C. Eosinophilic gastritis
   D. Exercise-induced asthma
   E. Hypereosinophilic syndrome

II. Chronic obstructive pulmonary disease (COPD)
   A. A single phase IIa study compared benralizumab to placebo in patients with COPD and showed there was no difference in rates of exacerbations; therefore, there is insufficient evidence in the safety and efficacy of benralizumab (Fasenra) for use in patients with COPD.

References

1. Fasenra Pen [Prescribing Information]. Wilmington, DE: AstraZeneca LP. October 2019.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: http://www.ginasthma.org. Accessed April 2018.
4. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014; 7: 53–65.
5. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613. doi: 10.1080/03007995.2017.1347091. Epub 2017 Jul 19.
6. The Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2017. Available from: www.ginasthma.org.

Policy Implementation/Update:

Action and Summary of Changes	Date
New policy	02/2020