

Fasenra® (benralizumab)

When requesting Fasenra® (benralizumab), the individual requiring treatment must be diagnosed with the following FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication

- Fasenra® (benralizumab) is indicated for add-on maintenance treatment of individuals with severe asthma having an eosinophilic phenotype.

Approved Off-label Compendial use

- None

Coverage Guidelines

Severe Asthma with an Eosinophilic Phenotype

Initial authorization:

The patient must meet all of the following criteria for initial authorization:

- Patient must be at least 12 years of age or older
- Fasenra must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
- Patient has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks
- Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND
 - o At least ONE of the following:
 - Inhaled long-acting beta agonist (LABA) [e.g., Serevent Diskus]; OR
 - Inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; OR
 - Leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; OR
 - Theophylline
 - NOTE: Use of a combination inhaler containing both ICS and a LABA would fulfill the requirement.
 - **EXCEPTION** to the requirement for a trial to one additional asthma controller/maintenance medication is if the patient already has been

receiving anti-IL-5 therapy (e.g. Cinqair and Nucala) in combination with an ICS for at least 3 consecutive months.

- Patient's asthma is uncontrolled defined by ONE of the following:
 - o The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o The patient experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
 - o Patient has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Patient has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o The patient's asthma worsens upon tapering of oral corticosteroids therapy

Approval duration: 6 months

Reauthorization:

The patient must meet all of the following for renewal:

- The patient has already received at least 6 months of therapy with Fasenra (NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Fasenra should be considered under initial criteria)
- Patient continues to receive therapy with one inhaled corticosteroid (ICS) or on ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- The patient has responded to Fasenra therapy as determined by the prescribing physician (e.g., decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency room visits, or physician visits due to asthma; decreased requirement for oral corticosteroids therapy)

Approval duration: 12 months

Dosing Guidelines

The recommended dose is 30 mg by subcutaneous (SC) injection once every 4 weeks for the first 3 doses, followed by 30 mg SC once every 8 weeks thereafter.

References

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7. Brightling CE, Bleecker ER, Panettieri RA, et al. Benralizumab for chronic obstructive pulmonary disease and sputum eosinophilia: a randomized, double-blind, placebo-controlled, phase 2a study. *Lancet Respir Med*. 2014;2(11):891-901.
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