Fasenra® (benralizumab)

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

FDA-Approved Indication

Fasenra is indicated for the add-on maintenance treatmen tof pateints with severe astham aged 12 years and older, and with an eosinophilic phenotype.

Coverage Guidelines

Severe Asthma with an Eosinophilic Phenotype

Initial authorization:
The individual must meet **all** of the following criteria for approval:

- Has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interluekin-5 therapy (e.g., Nucala, Cinqair)
- Has received at least 3 consecutive months of following combination therapy:
    - An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND an anti-interleukin-5 therapy (e.g., Cinqair, Nucala)

      OR

    - An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND at least one additional asthma controller/maintenance medication (e.g., inhaled long-acting $beta_2$ agonist (LABA) [e.g., Serevent Diskus]; inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; theophylline)

      OR

    - A combination inhaler containing both an inhaled corticosteroid and a long-acting $beta_2$ agonist (e.g., Symbicort, Advair, Dulera)

- Asthma is uncontrolled defined by ONE of the following:
    - Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR

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- Has experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
- Has a forced expiratory volume in 1 second (FEV_1) less than 80% predicted; OR
- Has an FEV_1/forced vital capacity (FVC) less than 0.80; OR
- Asthma worsens upon tapering of oral corticosteroids therapy

- Is 12 years of age or older
- Fasenra is prescribed by or in consultation with an allergist, immunologist, or pulmonologist

Reauthorization:

The patient must meet **all** of the following for approval

- Has already received at least 6 months of Fasenra therapy *(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)*
- Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir, RespiClick, Arnuity)
- Has responded to Fasenra therapy (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 (initial): 6 months
Approval duration (renewal): 12 months

Dosing Guidelines

The recommended dose of Fasenra 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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13. FitzGerald JM, Bleecker ER, Menzies-Gow A, et al. Predictors of enhanced response with benralizumab for patients with severe asthma: pooled analysis of the SIROCCO and CALIMA studies. *Lancet Respir Med*. 2018;6(1):51-64.

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