

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 treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype.

Coverage Guidelines

Severe Asthma

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 Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels (i.e., Cinqair, Dupixent, Nucala, Tezspire, Xolair);
- Has received at least 3 consecutive months of combination therapy with an inhaled corticosteroid and one additional asthma controller/maintenance medication (e.g., monoclonal antibody therapies, inhaled long-acting beta₂-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, a combination inhaler containing both an inhaled corticosteroid and a long acting beta₂-agonist);
- Asthma is/was uncontrolled prior to starting Fasenra or another monoclonal antibody therapy (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair) defined by ONE of the following:
 - o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o Has experienced one or more asthma exacerbations requiring hospitalization, emergency room visits, or urgent care visits in the previous year; OR
 - o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o 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, urgent care visits or medical clinic visits due to asthma; decreased requirement for oral corticosteroids therapy).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Recommendation

The recommended dose of Fasenra is 30 mg administered once every 4 weeks for the first 3 doses, and then once every 8 weeks thereafter by subcutaneous injection.

References

1. Fasenra™ subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
2. Bleecker ER, Fitzgerald JM, Chanez P, et al. Efficacy and safety of Fasenra for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2 -agonists (SIROCCO): a randomized, multicentre, placebo-controlled phase 3 trial. *Lancet*. 2016;388:2115-2127.
3. Fitzgerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomized, double-blind, placebo-controlled phase 3 trial. *Lancet*. 2016;388:2128-2141.
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5. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2019. Available at: <http://www.ginasthma.org>. Accessed on: March 15, 2023.
6. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
7. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society Guideline. *Eur Respir J*. 2020;55:1900588.
8. 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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12. Shomali W, Gotlib J. World Health Organization-defined eosinophilic disorders: 2019 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2019;94(10):1149-1167.