

Fasenra® (benralizumab)

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

FDA-Approved Indications

Asthma

Fasenra is indicated for the add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.

Eosinophilic Granulomatosis with Polyangiitis

Fasenra is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis.

Coverage Guidelines

Severe Asthma

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

- Is 6 years of age or older;
- Has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 6 weeks or prior to treatment with Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels (e.g., Cinqair, Dupixent, Ebglyss, Adbry, Nemluvio, 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, 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 exacerbation(s) 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 corticosteroid therapy;
- Fasenra is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

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

- 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

Eosinophilic Granulomatosis with Polyangiitis

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

- Is 18 years of age or older;
- Has active, non-severe disease, defined as vasculitis without life- or organ-threatening manifestations;
- Is currently receiving a systemic corticosteroid (e.g., prednisone) and has been on therapy for at least 4 weeks;
- Has a blood eosinophil count of greater than or equal to 150 cells per microliter within the previous 4 weeks or prior to treatment with Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels (i.e., Cinqair, Dupixent, Nucala, Tezspire, Xolair);
- Fasenra is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist.

The patient must meet both of the following criteria for re-authorization:

- Has already received at least 9 months of Fasenra therapy (*NOTE: Patients who have received less than 9 months of therapy or those who are restarting therapy with Fasenra should be considered under initial criteria*);
- Has responded to Fasenra therapy (e.g., reduced rate of relapses, corticosteroid dose reduction, or reduced eosinophil levels).

Approval duration (initial): 9 months

Approval duration (renewal): 12 months

Dosing Recommendations

Asthma

Adult and Adolescent Patients 12 Years of Age and Older:

The recommended dose is 30 mg administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.

Pediatric Patients 6 Years to 11 Years of Age:

Weighing less than 35 kg: The recommended dose is 10 mg administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.

Weighing 35 kg or more: The recommended dose is 30 mg administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.

Eosinophilic Granulomatosis with Polyangiitis

The recommended dose is 30 mg administered once every 4 weeks by subcutaneous injection.

References

1. Fasenra® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; September 2024.
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 randomised, 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.
4. Nair P, Wenzel S, Rabe KF, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med*. 2017;376(25):2448-2458.
5. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2024. Available at: <http://www.ginasthma.org>. Accessed on: September 20, 2024.
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.
9. Criner GJ, Celli BR, Brightling CE, et al. Benralizumab for the prevention of COPD exacerbations. *N Engl J Med*. 2019;381(11):1023-1034.
10. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2024 report. Global Initiative for Chronic Obstructive Lung Disease, Inc. Available from: <http://goldcopd.org/>. Accessed on April 9, 2024.
11. Kuang FL, Legrand F, Mikiya M, et al. Benralizumab for PDGFRA-negative hypereosinophilic syndrome. *N Engl J Med*. 2019;380(14):1336-1346.
12. Shomali W, Gotlib J. World Health Organization and international consensus classification of eosinophilic disorders: 2024 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2024;99(5):946-968.
13. Wechsler ME, Nair P, Terrier B, et al. Benralizumab versus mepolizumab for eosinophilic granulomatosis with polyangiitis. *New Engl J Med*. 2024;390(10):911-921.
14. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis Rheumatol*. 2021;73(8):1088-1105.
15. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis*. 2024;83(1):30-47.