

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.

Hypereosinophilic Syndrome

Fasenra is indicated for the treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome without an identifiable non-hematologic secondary cause.

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 alter 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).

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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 alter blood eosinophil levels (i.e., Adbry, Cinqair, Dupixent, Ebglyss, Nemluvio, 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).

Hypereosinophilic Syndrome

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

- Is 12 years of age or older;
- Has FIP1L1-PDGFR α -negative disease;
- Does not have an identifiable non-hematologic secondary cause of hypereosinophilic syndrome (e.g., drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy);
- Has/had a blood eosinophil level greater than or equal to 1,000 cells per microliter prior to treatment with any monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Adbry, Cinqair, Dupixent, Ebglyss, Nemludio, Nucala, Tezspire, Xolair);
- Has tried at least one other treatment for hypereosinophilic syndrome for at least 4 weeks (e.g., systemic corticosteroids, hydroxyurea, cyclosporine, imatinib, or pegylated-interferon);
- 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 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*);
- Has responded to Fasenra therapy (e.g., decreased number of flares, improved fatigue, reduced corticosteroid requirements, or decreased eosinophil levels).

Approval duration (initial): EGPA: 9 months; other indications 6 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/Hypereosinophilic Syndrome

The recommended dose is 30 mg administered subcutaneously once every 4 weeks.

References

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