benralizumab (Fasenra) prefilled syringe

Commercial Medical Benefit Drug Policy

Place of Service
Home Infusion Administration
Infusion Center Administration
Office Administration
Outpatient Facility Infusion Administration

Drug Details

USP Category: RESPIRATORY TRACT/PULMONARY AGENTS
Mechanism of Action: Interleukin-5 receptor antagonist monoclonal antibody
HCPCS:
J0517:Injection, benralizumab, 1 mg
How Supplied:
10 mg/0.5 mL or 30 mg/mL solution in a single-dose prefilled syringe

Condition(s) listed in policy *(see coverage criteria for details)*

- Eosinophilic Granulomatosis with Polyangiitis (EGPA) - formerly known as Churg-Strauss syndrome
- Severe Eosinophilic Asthma

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Fasenra prefilled syringes are managed under the Medical Benefit. Please include medical rationale why the patient cannot use the self-administered Fasenra autoinjector in the home. The Fasenra autoinjector can be obtained through the patient's pharmacy benefit. Please refer to the "Self-Administered Drugs" medical benefit drug policy for more information.

Members with the following plans: **PPO, Direct Contract HMO, and when applicable, ASO, Shared Advantage, HMO (non-direct)** may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

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For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION

MCG Care Guidelines, 19th edition, 2015

ADMINISTRATION OF FASENRA IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted)*

1. Patient is receiving their first infusion of Fasenra or is being re-initiated on Fasenra after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.*

OR

Additional clinical monitoring is required during administration as evidenced by one of the following:

2. Patient has experienced a previous severe adverse event on Fasenra based on documentation submitted.
3. Patient continues to experience moderate to severe adverse events on Fasenra based on documentation submitted, despite receiving premedication such as acetaminophen, steroids, diphenhydramine, fluids, etc.
4. Patient is clinically unstable based on documentation submitted.
5. Patient is physically or cognitively unstable based on documentation submitted.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Eosinophilic Granulomatosis with Polyangiitis (EGPA) - formerly known as Churg-Strauss syndrome

Meets medical necessity if all the following are met:

1. Age is consistent with the FDA-approved indication (18 years and older)
2. Prescribed by or in consultation with an immunologist
3. Patient has relapsing or refractory disease despite treatment with oral corticosteroid (e.g., prednisone, prednisolone) or immunosuppressive therapy (e.g., azathioprine, methotrexate, mycophenolate mofetil)
4. ***Effective 2/1/2026 and after:*** Not being used in combination with other targeted immunomodulators for EGPA (e.g. Nucala)

Covered Doses:
Up to 30 mg given once every 4 weeks

Coverage Period:
Initial: 6 months
Reauthorization: Yearly if patient is responding to Fasenra

ICD-10:
M31.0

Severe Eosinophilic Asthma

Meets medical necessity if all the following are met:

Initial:

1. Age is consistent with FDA approved indication (6 years of age and older)
2. Eosinophil blood count of at least 150 cells/µL
3. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (LTRA)
4. Meets one (1) of the following within the past year (a, b, or c):
   a. One or more acute asthma-related ED visit(s)
   b. One or more acute inpatient visits where asthma was the principal diagnosis,
   c. Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids
5. Will not be used in combination with another biologic medication for asthma (e.g., Cinqair, Dupixent, Nucala, Xolair, or Tezspire)

Reauthorization:

1. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment
2. Provider attestation that asthma symptoms have improved and/or controlled while on Fasenra

Covered Doses:

Up to 30 mg given subcutaneously every 4 weeks for first 3 doses, followed by once every 8 weeks

Coverage Period:

Initial: 6 months

Reauthorization: Yearly

ICD-10:

J45.20-J45.998

References

1. AHFS. Available by subscription at http://www.lexi.com
2. DrugDex. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
3. Fasenra (benralizumab) Prescribing Information. AstraZeneca, Wilmington, DE: August, 2025
4. Global Initiative for Asthma. (2025). Global strategy for asthma management and prevention. Updated July 2025. Available from https://ginasthma.org

Review History

Date of Last Annual Review: 4Q2025

Changes from previous policy version:

- Severe eosinophilic asthma: Removed specialist requirement (Rationale: Prescribing patterns consistent with expected specialists)
- Effective 2/1/2026 and after: For EGPA: will require use not in combination with other targeted immunomodulators. Rationale: ensure appropriate use

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee