Pharmacy Medical Necessity Guidelines:
Fasenra® (benralizumab) Pen (auto-injector)

Effective: March 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Fasenra (benralizumab) is an interleukin-5 alpha directed cytolytic monoclonal antibody (IgG1, kappa) indicated for:

- **Maintenance treatment of severe asthma**
  Add-on maintenance treatment of patients with severe asthma aged 6 years and older and with an eosinophilic phenotype. Fasenra (benralizumab) is not indicated for treatment of other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus.
- **Eosinophilic granulomatosis with polyangiitis**
  The treatment of adult patients with eosinophilic granulomatosis with polyangiitis

COVERAGE GUIDELINES

The plan may authorize coverage of Fasenra Pen (auto-injector) for Members when **ALL** of the following criteria are met:

Asthma

Initial Authorization Therapy

1. Documented diagnosis of severe asthma of eosinophilic phenotype as determined by one of the following:
   a. An eosinophilic phenotype confirmed by a blood eosinophil level of at least 150 cells/mcL within the past 12 months
   b. Current treatment with an alternative biologic indicated for moderate to severe allergic or eosinophilic asthma
   c. Patient is dependent on systemic corticosteroids

AND

2. Patient is at least 6 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

4. Documentation the patient is currently maintained on a maximally tolerated inhaled corticosteroid plus at least one other asthma maintenance medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist)

AND

5. The patient will not be concurrently treated with an alternative biologic for asthma

Reauthorization Criteria

1. Documented diagnosis of severe asthma of eosinophilic phenotype

AND

2. Patient is at least 6 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by **one (1)** of the following:
   a. Increase in percent predicted Forced Expiratory Volume (FEV1) from pretreatment baseline

b. Reduction in the dose of inhaled corticosteroids required to control asthma
c. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency department/urgent care visits)
d. Reduction in asthma symptoms (e.g., chest tightness, coughing, shortness of breath, or nocturnal awakenings)
e. Reduction in the use of oral corticosteroids to treat and/or prevent asthma exacerbations

AND

5. The patient will not be concurrently treated with an alternative biologic for asthma

Eosinophilic granulomatosis with polyangiitis

Initial Authorization Criteria

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist

AND

4. Documentation of **one (1)** of the following:
   a. The patient is stable on corticosteroids
   b. Contraindication to corticosteroids

AND

5. Documentation the patient's disease has relapsed or is refractory to standard of care therapy (i.e., corticosteroid treatment with or without immunosuppressive therapy)

Reauthorization Criteria

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist

AND

4. Documentation the patient has experienced a therapeutic response as defined by at least **one (1)** of the following:
   a. A reduction in the frequency and/or severity of relapses
   b. A reduction or discontinuation of doses of corticosteroids
   c. Disease remission

LIMITATIONS

- Initial approval of Fasenra will be authorized for six (6) months. Reauthorization of Fasenra will be provided in 12-month intervals.
- Patients new to the plan stable on Fasenra should be reviewed against Reauthorization Criteria.

CODES

None

REFERENCES

1. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. National Heart, Lung, and Blood Institute (NHLBI) & National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group (EPR-4). 2020. Accessed April 17, 2024.
3. National Heart, Lung, and Blood Institute (NHLBI) & National Asthma Education and Prevention Program (NAEPP). Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2007. Accessed April 17, 2024.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention - GINA Report Updated 2023. 2023. Accessed April 17, 2024

5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. Eur Respir J. 2014 Feb; 43(2):343-373.
6. Chun EJ, Zhang HP, Lv Yan, et al. The Asthma Control Test and Asthma Control Questionnaire for assessing asthma control: systemic review and meta -analysis. J Allergy Clin Immunol. 2013 Mar;131(3):695-703.

APPROVAL HISTORY

September 13, 2023: Reviewed by Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- May 14, 2024: Added the option for documentation that the patient is dependent on systemic corticosteroids for confirmation of diagnosis. Updated age requirements based on the expanded indication in patients at least 6 years of age (eff 6/1/204).
- May 13, 2025: Added coverage criteria for the supplemental indication in eosinophilic granulomatosis with polyangiitis (eff 6/1/25).
- February 10, 2026: For EGPA, removed documentation the patient has at least two (2) disease characteristics of EGPA (eff 3/1/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services