Harvard Pilgrim Health Care | TUFTS Health Plan

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

Effective: September 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Fasenra (benralizumab) Pen (autoinjector) 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
- **Hypereosinophilic Syndrome**
  The treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome without an identifiable non-hematologic secondary cause

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Fasenra Pen for Members when **ALL** of the following criteria are met:

Asthma

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of severe asthma with a pre-treatment peripheral blood eosinophil level greater than or equal to 150 cells per microliter

AND

2. Patient is six (6) years of age or older

AND

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

AND

4. Documentation of **one (1)** of the following within the previous 12 months:
   a. History of two (2) or more asthma exacerbations requiring systemic corticosteroids
   b. Prior asthma-related hospitalizations

AND

5. Documentation of history of failure to a minimum three (3) month trial with 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), unless contraindicated

AND

6. Documentation the requested medication will be used as add-on maintenance therapy with 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), unless contraindicated)

AND

7. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g., dupilumab)

Reauthorization Criteria

1. Documented diagnosis of severe asthma of eosinophilic phenotype

AND

2. Patient is six (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 at least **one (1)** of the following:
    a. Increase in percent 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/hospitalizations)
    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. Documentation the requested medication will be used as add-on maintenance therapy with a maximally tolerated inhaled corticosteroid plus at least one other asthma medication (e.g., long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist), unless contraindicated

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g., dupilumab)

Eosinophilic granulomatosis with polyangiitis

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of eosinophilic granulomatosis with polyangiitis

AND

2. Patient is 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 been stable on oral corticosteroid therapy for a minimum of four (4) weeks, unless contraindicated

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)

AND

6. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g., dupilumab)

Reauthorization Criteria

1. Documented diagnosis of eosinophilic granulomatosis with polyangiitis

AND

2. Patient is 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 clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

5. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g., dupilumab)

Hypereosinophilic Syndrome

Initial Authorization Criteria

1. Submission of medical charts documenting a diagnosis of hypereosinophilic syndrome

AND

2. Documentation the patient has been diagnosed for at least six (6) months

AND

3. Documentation that non-hematologic secondary causes (e.g., parasitic, allergic) have been ruled out

AND

4. Documentation the patient does not have FIP1-like1-platelet-derived growth factor receptor alpha (FIP1L1-PDGFRA) kinase positive hypereosinophilic syndrome

AND

5. Documentation of a pre-treatment blood eosinophil count greater than or equal to 1,000 cells per microliter

AND

6. Documentation of a history of two (2) or more hypereosinophilic syndrome flares within the previous 12 months (clinical manifestation or laboratory abnormality that resulted in an increase or addition of oral corticosteroids, or an increase or addition of new cytotoxic and/or immunosuppressive therapy)

AND

7. Patient is 12 years of age or older

AND

8. Prescribed by or in consultation with an allergist, immunologist, pulmonologist, dermatologist, or gastroenterologist

AND

9. Documentation of history of failure to a minimum four (4) week with one (1) of the following, unless contraindicated: Oral corticosteroid, oral immunosuppressant, or cytotoxic therapeutic agent

AND

10. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g. dupilumab)

Reauthorization Criteria

1. Documented diagnosis of hypereosinophilic syndrome

AND

2. Patient is 12 years of age or older

AND

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

AND

4. Documentation the patient has experienced a clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

5. Documentation the patient is not receiving the requested medication in combination with any of the following:
    a. Anti-interleukin-5 therapy (e.g., mepolizumab, resilizumab)
    b. Anti-IgE therapy (e.g., omalizumab)
    c. Thymic stromal lymphopoietin (TSLP) inhibitor (e.g., tezepelumab)
    d. Anti-interleukin 4 therapy (e.g. dupilumab)

Limitations

1. Initial approval of Fasenra Pen will be authorized for six (6) months. Reauthorization of Fasenra Pen will be provided in 12-month intervals.
2. Patients new to the plan stable on Fasenra Pen should be reviewed against Reauthorization Criteria. Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against Initial Authorization Criteria.

Codes

None

References

1. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.
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 And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- May 9, 2023: No changes
- May 14, 2024: Updated age requirements to at least 6 years of age (eff 6/1/24).
- May 13, 2025: Added coverage criteria for the supplemental indication in eosinophilic granulomatosis with polyangiitis (eff 6/1/25).
- June 9, 2026: For Asthma added submission of medical charts confirming diagnosis (Initial), removed current treatment with an alternative respiratory biologic as confirmation of diagnosis (Initial), added severity requirements (history of exacerbations or hospitalization), separated confirmation of history of failure of inhaler prerequisites and requested use as add-on therapy to inhalers (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), enhanced concurrent therapy language (Initial and Reauthorization), added confirmation treatment will be used as add-on therapy (Reauthorization), and added aubmission of medical charts confirming objective reauthorization criteria (Reauthorization). For EGPA added submission of medical charts confirming diagnosis (Initial), added minimum treatment duration of non-biologic prerequisites (Initial), added concurrent therapy language (Initial and Reauthorization), added submission of medical charts confirming broad reauthorization criteria (Reauthorization), and updated objective reauthorization criteria to broad reauthorization criteria (Reauthorization). Added limitation statement that members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria. Administrative update to remove Carelink from the Medical Necessity Guideline template (eff 9/1/26).
- August 11, 2026: Removed submission of medical records requirements for response to therapy in Reauthorization Criteria. Added coverage criteria for the supplemental indication in hypereosinophilic syndrome (eff 9/1/26).

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.