Benralizumab (Fasenra®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Fasenra is indicated for:

A. Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.

Limitations of Use:
Not indicated for relief of acute bronchospasm or status asthmaticus

B. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Asthma
   1. For initial requests:
      i. Chart notes or medical record documentation showing baseline blood eosinophil count, or dependance on systemic corticosteroids if applicable.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. EGPA
   1. For initial requests:
      i. Chart notes or medical record documentation showing pretreatment blood eosinophil count.
      ii. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.
   2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

III. PRESCRIBER SPECIALTIES

For the indication of asthma: This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

IV. CRITERIA FOR INITIAL APPROVAL

A. Asthma

1. Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma in the past year.

2. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
   - i. Member is 6 years of age or older.
   - ii. Member meets either of the following criteria:
     - a. Member has a baseline blood eosinophil count of at least 150 cells per microliter
     - b. Member is dependent on systemic corticosteroids
   - iii. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
     - a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
     - b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
     - c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
   - iv. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
     - a. High dose inhaled corticosteroid
     - b. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   - v. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a history or the presence of a blood eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
3. Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. Member has at least two of the following disease characteristics of EGPA:
   - i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
   - ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
   - iii. Pulmonary infiltrates, non-fixed
   - iv. Sino-nasal abnormality
   - v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
   - vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
   - vii. Alveolar hemorrhage (by bronchoalveolar lavage)
   - viii. Palpable purpura
   - ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)

5. Member has had at least one relapse (i.e., requiring increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with the requested medication or has a refractory disease.

V. CONTINUATION OF THERAPY

A. Asthma

Authorization of 12 months may be granted for treatment of severe asthma when all of the following criteria are met:

1. Member is 6 years of age or older.
2. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

Authorization of 12 months may be granted for continuation of treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a beneficial response to treatment with the requested medication as demonstrated by any of the following:
   i. A reduction in the frequency of relapses
   ii. A reduction or discontinuation of daily oral corticosteroid dose
   iii. No active vasculitis

VI. OTHER

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

MEDICATION QUANTITY LIMITS

Drug Name	Diagnosis	Maximum Dosing Regimen
Fasenra (Benralizumab)	Asthma	Route of Administration: Subcutaneous ≥12 Year(s) Initial: 30mg every 4 weeks for 3 doses Maintenance: 30mg every 8 weeks ≥6 to <12 year(s) ≥35kg Initial: 30mg every 4 weeks for 3 doses Maintenance: 30mg every 8 weeks ≥6 to <12 year(s) <35kg Initial: 10mg every 4 weeks for 3 doses

		Maintenance: 10mg every 8 weeks
Fasenra (Benralizumab)	Eosinophilic Granulomatosis with Polyangiitis	Route of Administration: Subcutaneous ≥18 year(s) 30mg every 4 weeks

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. *N Engl J Med.* 2017;376:2448-2458.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06-WMS.pdf. Accessed March 8, 2024.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 8, 2024.
5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA*. 2020;324(22): 2301-2317.
6. AstraZeneca. Efficacy and Safety of Benralizumab in EGPA Compared to Mepolizumab. (MANDARA) Available from https://clinicaltrials.gov/ct2/show/record/NCT04157348. NLM identifier: NCT04157348. Accessed September 20, 2024.
7. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force Recommendations for evaluation and management. Eur J Intern Med. 2015;26(7):545-553.
8. 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):1366-1383.

EFFECTIVE DATE 4/2/2025