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

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 Indications

- Fasenra is indicated for add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype.
- Fasenra is indicated for treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Fasenra is indicated for treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause.

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

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

DOCUMENTATION

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

- Chart notes or medical record documentation showing pretreatment blood eosinophil count, or dependance on systemic corticosteroids, if applicable.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.

Continuation requests
Chart notes or medical record documentation supporting improvement in asthma control.

EGPA
Initial requests

- Chart notes or medical record documentation showing pretreatment blood eosinophil count or percentage of blood eosinophil level (where applicable).

- 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.

Continuation requests
Chart notes or medical record documentation supporting beneficial response to treatment.

HES
Initial requests
- FIP1L1-PDGFRA fusion gene test results.
- Chart notes or medical record documentation showing pretreatment blood eosinophil count.
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests
- FIP1L1-PDGFRA fusion gene test results.
- Chart notes or medical record documentation supporting improvement in HES control.

EXCLUSIONS

Coverage will not be provided for treatment of HES for members with any of the following exclusions:
- HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus [HIV] infection, non-hematologic malignancy).
- FIP1L1-PDGFRA kinase-positive HES.

PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with one of the following:
- Asthma: allergist/immunologist or pulmonologist.
- Eosinophilic granulomatosis with polyangiitis: allergist/immunologist, pulmonologist, or rheumatologist
- Hypereosinophilic syndrome: allergist/immunologist, hematologist, or cardiologist

COVERAGE CRITERIA

Asthma

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 12 months. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid [ICS] and additional controller) in combination with the requested medication.

Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
- Member is 6 years of age or older.
- Member meets either of the following criteria:
  - Member has a baseline blood eosinophil count of at least 150 cells per microliter.
  - Member is dependent on oral systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past 12 months:
  - Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
  - One or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s)

  - Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
- Member has inadequate asthma control despite adherence to current treatment with both of the following medications at optimized doses:
  - High-dose ICS (see Appendix A and Appendix B)
  - Additional controller (i.e., long acting beta2-agonist [LABA], long-acting muscarinic antagonist [LAMA], leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (e.g., ICS and additional controller) in combination with the requested medication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Authorization of 12 months may be granted for members 18 years of age or older who have previously received a biologic drug (e.g., Nucala) indicated for EGPA in the past 12 months.

Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:
- Member is 18 years of age or older.
- 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%.
- Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
- Member has at least two of the following disease characteristics of EGPA:
  - Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
  - Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
  - Pulmonary infiltrates, non-fixed
  - Sino-nasal abnormality
  - Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
  - Glomerulonephritis (hematuria, red cell casts, proteinuria)
  - Alveolar hemorrhage (by bronchoalveolar lavage)
  - Palpable purpura
  - Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
- Member has had at least one relapse (i.e., requiring increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 24 months prior to starting treatment with the requested medication or has refractory disease.

Hypereosinophilic Syndrome (HES)

Authorization of 12 months may be granted for treatment of HES when all of the following criteria are met:
- Member is 12 years of age or older.
- Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter.
- Member will not use the requested medication as monotherapy.
- Member has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy).
- Member has experienced at least two HES flares within the past 12 months.

CONTINUATION OF THERAPY

Asthma

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

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

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:

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

Hypereosinophilic Syndrome (HES)

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

- Member is 12 years of age or older.
- Member has experienced a reduction in HES flares since starting treatment with the requested medication.

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.

APPENDIX

Appendix A. Examples of High-Dose ICS (Alone or in Combination with LABA) for Adults and Adolescents (12 Years and Older)

Drug	Dosage Form	Total Daily Dose
Beclomethasone dipropionate	Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA)	>1000 mcg
Beclomethasone dipropionate	Dry-powder inhaler (DPI) or pMDI, extra-fine particle size HFA	>400 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>800 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>320 mcg
Fluticasone furoate	DPI	200 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>500 mcg
Mometasone furoate	DPI or pMDI, standard particle size HFA	>400 mcg

Appendix B. Examples of High-Dose ICS (Alone or in Combination with LABA) for Children 6 to 11 Years

Drug	Dosage Form	Total Daily Dose
Beclomethasone dipropionate	pMDI, standard particle size HFA	>400 mcg
Beclomethasone dipropionate	pMDI, extra-fine particle size HFA	>200 mcg
Budesonide	DPI or pMDI, standard particle size HFA	>400 mcg
Budesonide	Nebules	>1000 mcg
Ciclesonide	pMDI, extra-fine particle size HFA	>160 mcg
Fluticasone propionate	DPI or pMDI, standard particle size HFA	>200 mcg
Mometasone furoate	pMDI, standard particle size HFA	200 mcg

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).

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EFFECTIVE DATE 12/1/2026

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