POLICY Document for FASENRA (benralizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Site of Care
- Policy information specific to site of care (outpatient, hospital outpatient, home infusion)

Section 3: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
ASTHMA

PREFERRED PRODUCTS: FASENRA, NUCALA, XOLAIR, TEZSPIRE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the asthma products specified in this policy. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Asthma Products

	Product(s)
Preferred*	• **Fasenra** (benralizumab) • **Nucala** (mepolizumab) • **Xolair** (omalizumab) • **Tezspire** (benralizumab)
Targeted	• **Cinqair** (reslizumab)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for the targeted product is provided when the following criteria is met:

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Site of Care

Site of Care Criteria
Fasenra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated.

Brand Name	Generic Name	Dosage Form
Fasenra	benralizumab	subcutaneous

Criteria For Approval For Administration In Outpatient Hospital Setting

This policy provides coverage for provider administered Fasenra in an outpatient hospital setting for up to 45 days when a member is new to therapy or is reinitiating therapy after not being on therapy for at least 6 months.

This policy provides coverage for administration of Fasenra in an outpatient hospital setting for a longer course of treatment when ANY of the following criteria are met:

- The member has experienced an adverse reaction to the drug that did not respond to conventional interventions (eg, acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration.
- The member is medically unstable (eg respiratory, cardiovascular, or renal conditions).

- The member has significant behavioral issues and/or physical or cognitive impairment that would impact the safety of drug administration AND the patient does not have access to a caregiver.
- Alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) are greater than 30 miles from the member's home.
- The member is less than 14 years of age.

For situations where administration of Fasenra does not meet the criteria for outpatient hospital administration, coverage for Fasenra is provided when administered in alternative sites such as; physician office, home infusion or ambulatory care.

Fasenra Pen (autoinjector) are not targeted in this policy.

Required Documentation

The following information is necessary to initiate the site of care prior authorization review (where applicable):

- Medical records supporting the member has experienced an adverse reaction that did not respond to conventional interventions or a severe adverse event during or immediately after administration
- Medical records supporting the member is medically unstable
- Medical records supporting the member has behavioral issues and/or physical or cognitive impairment and no access to a caregiver
- Records supporting alternative infusion sites are greater than 30 miles from the member's home
- Medical records supporting the member is new to therapy

Section 3: Clinical Criteria

Specialty Guideline Management
Fasenra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Fasenra	benralizumab

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

This section of the document is organized by the drug or drugs covered by this criteria. Limitations of use for the drug are also identified here.

Fasenra

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

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

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

Limitations of Use

Not indicated for the relief of acute bronchospasm or status asthmaticus

Documentation

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

Asthma:

For initial requests:

- Chart notes or medical record documentation showing baseline 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.

For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

EGPA

For initial requests:

- 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. If therapy is not advisable, documentation of clinical reason to avoid therapy.

For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

Prescriber Specialties

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

Coverage Criteria

Asthma[1-5]

The requested drug will be covered with prior authorization when one (1) of the following criteria are met:

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.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 systemic corticosteroids.
- Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
  - 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 current treatment with both of the following medications at optimized doses:
  - High-dose inhaled corticosteroid
  - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Eosinophilic granulomatosis with polyangiitis (EGPA)[1,6-8]

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 2 years prior to starting treatment with the requested medication or has a refractory disease.

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 in the daily maintenance oral corticosteroid dose
Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, 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

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.

REFERENCES:

SECTION 1

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2. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
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4. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; March 2023.
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SECTION 2

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024

SECTION 3

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.
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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.