

# 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<sup>1</sup>

- 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-PDGFRα 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-PDGFRα 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-PDGFRα 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<sup>1-5</sup>

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)<sup>1,6-8</sup>

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)<sup>1,9,10</sup>

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)<sup>1</sup>

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)<sup>5</sup>

| Drug                        | Dosage Form                                                                                        | Total Daily Dose |
|-----------------------------|----------------------------------------------------------------------------------------------------|------------------|
| Beclomethasone dipropionate | Pressurized metered-dose inhaler (pMDI), standard particle size hydrofluoroalkane propellant (HFA) | >1000 mcg        |

| Drug                        | Dosage Form                                                    | Total Daily Dose |
|-----------------------------|----------------------------------------------------------------|------------------|
| 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<sup>5</sup>

| 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          |

## References

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2026.
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6. Efficacy and Safety of Benralizumab in EGPA Compared to Mepolizumab. (MANDARA). ClinicalTrials.gov identifier: NCT04157348. Updated February 3, 2026. Accessed March 12, 2026. <https://clinicaltrials.gov/ct2/show/record/NCT04157348>

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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.
9. Shomali W, Gotlib J. World Health Organization and International Consensus Classification of eosinophilic disorders: 2024 update on diagnosis, risk stratification, and management. *Am J Hematol.* 2024;99(5):946-968.
10. Butt NM, Lambert J, Ali S, et al. Guideline for the investigation and management of eosinophilia. *Br J Haematol.* 2017;176(4):553-572.