Reference number(s)
2419-A

Standard Medicare Part B 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[1]

Maintenance Treatment of Severe, Eosinophilic Asthma

Fasenra is indicated for the 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 for relief of acute bronchospasm or status asthmaticus

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Fasenra is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

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Documentation

The following documentation must be available, upon request, for all submissions:

Eosinophilic Asthma

Initial requests

- Chart notes or medical record documentation showing baseline blood eosinophil count.
- 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 benefit from therapy.

EGPA

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.

Continuation requests

Chart notes or medical record documentation supporting benefit from therapy.

Coverage Criteria

Eosinophilic Asthma[1-4]

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

- Member is 6 years of age or older.
- Member has a baseline (pre-treatment with a biologic indicated for asthma) blood eosinophil count of at least 150 cells per microliter.
- Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
    - Inhaled corticosteroid
    - Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline).

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- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair).

Eosinophilic Granulomatosis with Polyangiitis (EGPA)[1,5]

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 an 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 will not use requested medication concomitantly with other biologics indicated for EGPA (e.g., Nucala).

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested medication.

Eosinophilic Asthma

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

- Member is 6 years of age or older.
- The member is currently receiving therapy with Fasenra.
- Fasenra is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.
- Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair).

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.
- The member is currently receiving therapy with Fasenra.
- Fasenra is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.

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- Member will not use the requested medication concomitantly with other biologics indicated for EGPA (e.g., Nucala).

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for Fasenra.
- The available compendium
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update.
- Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Fasenra are covered.

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Fasenra to treat severe asthma can be found in the Global Initiative for Asthma (GINA) guidelines. For adults and adolescents 12 years of age and older, an anti-IL5 receptor antagonist can be a drug used when either medium dose maintenance inhaled corticosteroids with formoterol or medium to high dose maintenance inhaled corticosteroids with long-acting beta2-agonists are not controlling the patient's asthma.

References

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2024 update. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf. Accessed March 1, 2025.
3. 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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4. 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.
5. 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 March 16, 2025.

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