

<b>Reference number(s)</b>
2413-A

# SPECIALTY GUIDELINE MANAGEMENT

## FASENRA (benralizumab)

### 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 the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

##### *Limitations of Use:*

- Not for treatment of other eosinophilic conditions
- Not for relief of acute bronchospasm or status asthmaticus

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. For initial requests:
1. Member's chart notes or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.
  2. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
- B. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

#### III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

#### IV. CRITERIA FOR INITIAL APPROVAL

- A. Authorization of 6 months may be granted for members 12 years of age or older who have previously received a biologic drug (e.g., Dupixent, Nucala) indicated for asthma.
- B. Authorization of 6 months may be granted for treatment of severe asthma when all of the following criteria are met:
1. Member is 12 years of age or older.

2. Member meets either of the following criteria:
  - i. Member has a baseline blood eosinophil count of at least 150 cells per microliter
  - ii. Member is dependent on systemic corticosteroids
3. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
  - i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
  - ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
  - iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
4. Member has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
  - i. High dose inhaled corticosteroid
  - ii. Additional controller (i.e., long acting beta<sub>2</sub>-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
5. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

## V. CONTINUATION OF THERAPY

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

- A. Member is 12 years of age or older.
- B. Asthma control has improved on the requested medication as demonstrated by at least one of the following:
  1. A reduction in the frequency and/or severity of symptoms and exacerbations
  2. A reduction in the daily maintenance oral corticosteroid dose
- C. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

## VI. OTHER

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.

## VII. REFERENCES

1. Fasentra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
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. 2022 update. Available at: <https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf>. Accessed March 1, 2023.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: <https://annualmeeting.aaaai.org/>. Accessed March 1, 2023.

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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.