

STANDARD MEDICARE PART B 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 will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. CRITERIA FOR INITIAL APPROVAL

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

- A. Member has a baseline blood eosinophil count of at least 150 cells per microliter.
- B. 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:
 1. Inhaled corticosteroid
 2. Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)

III. CONTINUATION OF THERAPY

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

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

- A. The member is currently receiving therapy with Fasenra.
- B. Fasenra is being used to treat an indication enumerated in Section II.
- C. The member is receiving benefit from therapy.

IV. REFERENCES

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2019.

Reference number(s)
2419-A

2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2019 update. Available at: <https://ginasthma.org/reports/>. Accessed March 5, 2020.
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.