Reference number(s)
2419-A

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. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. For initial requests:
   1. Member's chart notes or medical record showing pretreatment blood eosinophil count, dependance on inhaled 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. 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 is 12 years of age or older.
B. Member has a baseline blood eosinophil count (pretreatment with a biologic indicated for asthma) of at least 150 cells per microliter.
C. 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 (i.e., long acting beta$_2$-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

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

IV. CONTINUATION OF THERAPY

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

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

A. Member is 12 years of age or older.
B. The member is currently receiving therapy with the requested medication.
C. The requested medication is being used to treat an indication enumerated in Section III.
D. The member is receiving benefit from therapy as defined by reduction in the frequency and/or severity of symptoms and exacerbations.
E. Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, or Xolair).

V. REFERENCES

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
2. 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.
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.
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.