Reference number(s)
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 or medical record showing pretreatment blood eosinophil count, dependance 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. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:
A. Member is 12 years of age or older.
B. Member meets either of the following criteria:
   1. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
   2. Member is dependent on systemic corticosteroids
C. Member has inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
   1. Inhaled corticosteroid
   2. Additional controller (long-acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)
D. Member will not use Fasenra as monotherapy.
E. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Xolair).

IV. CONTINUATION OF THERAPY

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

A. Member is 12 years of age or older.
B. Asthma control has improved on Fasenra treatment 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 not use Fasenra as monotherapy.
D. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Xolair).

V. OTHER

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.

VI. REFERENCES

1. Fasenra [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. 2019 update. Available at: https://ginasthma.org/reports/. Accessed March 5, 2021.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 5, 2021.