Effective Date: 12/2018
Revised: 4/20 Reviewed: 12/18, 7/19, 4/20 Scope: Medicaid

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 are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests: documentation of baseline blood eosinophil count and components of severity that classify asthma as severe
B. Continuation of therapy requests: documentation of improved 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. Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
C. Member has clinically documented severe asthma (see Appendix).
D. Member has asthma with an eosinophic phenotype with documentation of blood eosinophil count of ≥150 cells per microliter within 6 weeks of starting therapy.
E. Member is adherent to current treatment with both of the following medications at optimized doses for at least 2 months:

1. Inhaled corticosteroid
2. Additional controller medication (long acting beta$_2$-agonist, leukotriene modifier, or sustained-release theophylline)

F. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations).
G. Member will use Fasenra as add-on maintenance treatment.
H. Member will not use Fasenra concomitantly with other biologics (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. Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
C. Member is tolerating treatment.
D. Asthma control has improved/stabilized on Fasenra treatment from baseline as demonstrated by at least one of the following:
   1. A reduction in the frequency and/or severity of symptoms and exacerbations (e.g. decrease in hospitalizations, emergency department or urgent care visits)
   2. A reduction in the daily maintenance oral corticosteroid dose
E. Member will use Fasenra as add-on maintenance treatment.
F. Member will not use Fasenra concomitantly with other biologics (e.g., Cinqair, Dupixent, Nucala, Xolair).

II. QUANTITY LIMIT

Fasenra has a quantity limit of 1 syringe per 56 days, with post-limit of 3 syringes per 84 days.

III. APPENDIX

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma