

Policy: MBP 173.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Fasenra Prefilled Syringes (benralizumab)

I. Policy:

Fasenra Prefilled Syringes (benralizumab)

II. Purpose/Objective:

To provide a policy of coverage regarding Fasenra (benralizumab)

III. Responsibility:

- A. Medical Directors
- B. Medical Management
- C. Pharmacy Department

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards good medical treatment practiced by the general medical community;
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:

Fasenra (benralizumab), a humanized monoclonal antibody (IgG1, kappa), is an interleukin-5 antagonist. IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and an important component in the pathogenesis of asthma). Benralizumab, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Fasenra Prefilled Syringes (benralizumab) will be considered medically necessary when ALL of the following criteria are met:

- Prescribed by an allergist/immunologist or pulmonologist **AND**
 - Patient is 12 years of age or older **AND**
 - Medical record documentation of a diagnosis of severe eosinophilic asthma **AND** that Fasenra is being used as add-on maintenance treatment **AND**
 - Medical record documentation of blood eosinophil count ≥ 150 cells/microL ($0.15 \times 10^3/\mu\text{L}$) within the past 3 months **AND**
 - Medical record documentation of:
 - Intolerance to or not well controlled or very poorly controlled symptoms* despite at least a 3-month trial of high-dose inhaled corticosteroids and/or oral systemic corticosteroids plus a long-acting beta agonist **OR**
 - Two or more exacerbations in the previous 12 months requiring additional medical treatment (oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite current therapy with high-dose inhaled corticosteroids plus a long-acting beta agonist
- AND**
- Medical record documentation that individual is adherent to current therapeutic regimen and has demonstrated appropriate inhaler technique **AND**
 - Medical record documentation that known environmental triggers within the member's control have been eliminated **AND**
 - Medical record documentation that the medication will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Xolair (omalizumab), Nucala (mepolizumab), Dupixent (dupilumab), Cinqair (reslizumab), Tezspire (Tezepelumab))

Limitations:

- Fasenra is not indicated for treatment of other eosinophilic conditions.
- Fasenra is not indicated for the relief of acute bronchospasm or status asthmaticus.

***Measures of Disease Severity**

Measure	Not Well Controlled	Very Poorly Controlled
Symptoms	> 2 days per week	Throughout the day
Nighttime awakenings	1-3x/week	$\geq 4x/\text{week}$
Interference with normal activity	Some limitation	Extremely limited
SABA use for symptom control (not to prevent exercise-induced bronchospasm)	> 2 days/week	Several times per day
FEV1 (% predicted) or peak flow (% personal best)	60-80%	< 60%
Asthma Control Test (ACT) Score	16-19	≤ 15

AUTHORIZATION DURATION: Initial approval will be for **12 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of the following:

- Documentation that patient is not experiencing toxicity or worsening of disease **AND**
- Medical record documentation of at least one of the following:
 - Medical record documentation of continued disease improvement or lack of disease progression as evidenced by a reduction in asthma exacerbations (e.g. reduced use of rescue medications, reduced urgent care visits, reduced hospitalizations) **OR**
 - Medical record documentation of decreased oral corticosteroid use (if on maintenance treatment prior to Fasenra initiation)

QUANTITY LIMITS: Enter a 3-month auth for QL of 1 syringe (1mL) per 28 days. Remainder of the 12-month authorization duration and subsequent renewals, QL of 1 syringe (1mL) per 56 days.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 5/15/18

Revised: 6/26/18 (eosinophil count per DHS), 11/19/19 (prefilled syringe), 5/17/22 (asthma biologic verbiage), 5/11/23 (Medicaid business segment)

Reviewed: 4/22/19, 11/16/20, 10/4/21