Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 173.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Fasenra Prefilled Syringes (benralizumab)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

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 the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. 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

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 for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation that Fasenra is prescribed by an allergist/immunologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **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 x 10E3/uL) within the past 3 months **AND**
- Medical record documentation of ONE of the following:
    - 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	≥ 4x/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 for Fasenra 30 mg/mL, 0.5 mL for Fasenra 10 mg/0.5 mL) per 28 days. Remainder of the 12-month authorization duration and subsequent renewals, QL of 1 syringe (1mL for Fasenra 30 mg/mL, 0.5 mL for Fasenra 10 mg/0.5 mL) per 56 days.

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

- Medical record documentation that Fasenra is prescribed by an allergist/immunologist or pulmonologist **AND**
- Medical record documentation of age greater than or equal to 6 years **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 x 10E3/uL) within the past 3 months **AND**
- Medical record documentation of ONE of the following:
    - 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 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:

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Nighttime awakenings	1-3x/week	≥ 4x/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

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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.

REFERENCES:

1. Fasenra [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
2. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. 2023 July [cited 2023 Dec 26]. Available from: https://ginasthma.org/2023-gina-main-report/

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), 12/30/23 (references added), 6/3/24 (LOB carve out per Dec 2023 P&T), 8/19/24 (age update, QL, LOB table, taglines, removed Medicaid business segment)

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

MA UM Committee approval: 12/31/23, 8/30/24