STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Fasenra (benralizumab)
PAM-032

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	07/01/2021
Revision Number:	3	**Last Rev Date:**	07/21/2023
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/19/2024
Approved By:	Medicaid Clinical Advisory Committee	**Approved Date:**	04/16/2021

Overview

Medication: [1]	benralizumab
Brand Name:	Fasenra®
Pharmacologic Category:	Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa)

FDA-Approved Indication(s):	Add-on maintenance treatment of patients with severe asthma 12 years of age 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.

How Supplied:	• Single-dose prefilled syringe, 30 mg/mL • Also available as a single dose autoinjector, 30 mg/mL (trade name Fasenra® PEN) which is a pharmacy benefit item and is not included in this policy criteria.
Dosage and Administration:	• Initial: 30 mg every 4 weeks for the first 3 doses • Maintenance: 30 mg every 8 weeks thereafter
Benefit Category:	Medical

Descriptive Narrative

The Expert Panel 3 of the National Asthma Education and Prevention Program defines asthma as "a common chronic disorder of the airways that is complex and characterized by variable and recurring symptoms, airflow obstruction, bronchial hyperresponsiveness, and an underlying inflammation. The interaction of these features of asthma determines the clinical manifestations and severity of asthma and the response to treatment." [2]

Severe asthma is defined as requiring high-dose inhaled glucocorticoid, or continuous or near continuous oral glucocorticoid treatment to maintain asthma control, or never achieving control despite that treatment.[3]

Fasenra® is indicated as add-on treatment for patients 12 years of age and older with severe asthma with an eosinophilic phenotype. Eosinophils are a type of white blood cell which are primarily found in the tissues; however; they can accumulate in the peripheral blood or tissues

in a wide array of disease states, including when allergic reactions take place (including allergic asthma). This accumulation can cause airway inflammation, increasing the risk of severe asthma exacerbations.[4]

Abbreviations

AEC: Absolute eosinophil count, a measure of the number of eosinophils present in the peripheral blood. AEC is calculated as follows:

$$\left(\frac{white\ blood\ cell\ (WBC)\ count}{microL}\right) * (percentage\ of\ eosinophils) = AEC\ \left(expressed\ as\ \left(\frac{eosinophils}{microL}\right)\right)$$

FEV_1: Forced expiratory volume in one second. A measure of the maximal volume of air exhaled in the first second of a forced exhalation that follows a full inspiration, expressed in liters. In members with asthma, FEV_1 declines with clinical worsening of airway obstruction. The measured FEV_1 is usually expressed as a percent of the predicted value for determination of normality.

ICS: Inhaled corticosteroid. These are the foundation of long-term controller therapy in patients with severe asthma. Corticosteroids have anti-inflammatory activity (inflammation is an important component in the pathogenesis of asthma).

IgE: immunoglobulin E, which plays a central role in the pathogenesis of allergic diseases, including asthma. Anti-IgE therapy may be considered in patients whose asthma is inadequately controlled on high-dose glucocorticoids and LABAs, if there is objective evidence of sensitivity to a perennial allergen.

IL-4, IL-5: Interleukin 4 (IL-4) and 5 (IL-5) are potent chemoattractants for eosinophils. Monoclonal antibodies against these interleukins are available for treatment of severe eosinophilic asthma that is poorly-controlled with conventional therapy.

LABA: Long-acting $beta_2$ agonist, these agents relax bronchial smooth muscle and inhibit the release of mediators of immediate hypersensitivity from cells, especially mast cells (e.g., histamine, leukotrienes, and prostaglandin D2). LABAs are contraindicated for use as monotherapy and must be used in combination with ICS in the treatment of asthma.

LTMA: Leukotriene modifying agent, reduces asthmatic responses to bronchoprovocation challenge. May provide modest additive benefit when used as adjunctive therapy with ICS, but guidelines only recommend use in severe asthma if member does not tolerate LABA therapy, or if a contraindication to LABA therapy exists.

SABA: Short-acting $beta_2$-agonist. Potent bronchodilator approved for clinical use in asthma and obstructive lung disease. Inhaled, short-acting, selective $beta_2$ adrenergic agonists are the mainstay of acute asthma therapy, while inhaled, long-acting, selective $beta_2$ adrenergic agonists (in combination with inhaled glucocorticoids) play a role in long-term control of moderate to severe asthma.

Criteria

Prior authorization is required.

Fasenra® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of severe eosinophilic asthma, including an absolute eosinophil count (AEC) of **AT LEAST ONE** of the following:
    a. 150 cells/mcL or higher within the past 6 weeks; **AND/OR**
    b. 300 cells/mcL or higher within the past 12 months; **AND**
2. Member has an inadequate response after, or a documented intolerance to, a minimum of 3 months of adherent treatment with appropriate controller therapy, i.e., medium-to-high dose inhaled corticosteroid (ICS) in combination with either a long-acting $beta_2$ agonist (LABA) or a leukotriene modifying agent (LTMA) (if LABA is contraindicated or patient is intolerant to LABA therapy); **AND**
3. Documentation that member's asthma is not well-controlled, as indicated by **AT LEAST ONE** of the following:
    a. Asthma symptoms experienced more than 2 days per week despite adherent use of controller therapy (i.e., ICS-LABA or ICS-LTMA); **AND/OR**
    b. Spirometry measurement of FEV_1 (forced expiratory volume in one second) less than or equal to 80 percent predicted; **AND/OR**
    c. In the past 12 months, member has had two or more asthma exacerbations requiring oral or systemic corticosteroid treatment (or an increase in patient's current maintenance dose of oral corticosteroids), and/or an emergency office visit with specialist, an urgent care visit, or a hospital admission; **AND**
4. Member is 12 years of age or older; **AND**
5. Member does **NOT** have acute bronchospasm or status asthmaticus; **AND**
6. Fasenra® will not be used as monotherapy (i.e., member will continue treatment with ICS-LABA or ICS-LTMA); **AND**
7. Fasenra® will not be used in combination with Cinqair®, Dupixent®, Nucala®, Tezspire®, or Xolair®; **AND**
8. Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
9. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved regimen, regimen (including dosage) must be supported by clinical practice guidelines (supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling).

Fasenra® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of a positive clinical response to therapy [e.g., increase in FEV_1 (forced expiratory volume in one second) from baseline, decrease in the frequency of exacerbations, reduction in oral corticosteroid dosage if applicable, reduction in the use of rescue therapy;] **AND**
3. Fasenra® will not be used as monotherapy (i.e., member will continue treatment with medium-to-high dose inhaled corticosteroid and long-acting $beta_2$ agonist (ICS-LABA) or medium-to-high dose inhaled corticosteroid and a leukotriene modifying agent (ICS-LTMA); **AND**
4. Fasenra® will not be used in combination with Cinqair®, Dupixent®, Nucala®, Tezspire®, or Xolair®; **AND**
5. Prescribed by, or in consultation with, a pulmonologist, allergist, or immunologist; **AND**
6. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved regimen, regimen (including dosage) must be supported by clinical practice guidelines (supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling).

Approval Duration and Quantity Limits

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	One dose (30 mg) every 8 weeks (after initial 3-dose sequence)	One dose (30 mg) every 8 weeks

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
J0517	Injection, benralizumab, 1 mg

ICD-10	Description
J45.5	Severe persistent asthma
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus

NDC	Labeler	Dosage	Pkg Size	Pkg Qty	Units/Pkg
00310-1730-30	AstraZeneca Pharmaceuticals	1 mg	1	1	30

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Fasenra prescribing information (02/2021). Astra Zeneca Pharmaceuticals LP; Wilmington, DE. Available online at www.fasenrahcp.com. Accessed July 7, 2023.

[2] National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2007 Aug. Available from: www.ncbi.nlm.nih.gov/books/NBK7232/.

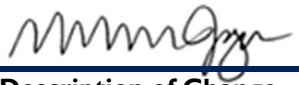
[3] Wenzel MD. Treatment of severe asthma in adolescents and adults. Hollingsworth MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed April 30, 2021.

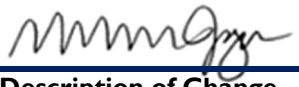
[4] Weller MD, Klion MD. Eosinophil biology and causes of eosinophilia. Rosmarin MD, Feldweg MD, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 1, 2021.

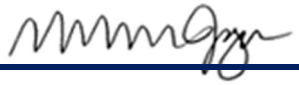
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Annual review. Added Tezspire to list of medications which are not to be used concurrently. Merged "Not medically necessary" section into initial criteria. Added to Overview section: "Limitations of Use: Not for treatment of other eosinophilic conditions. Not for relief of acute bronchospasm or status asthmaticus."	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/15/2022	CAC	Annual review. Formatting changes only.	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
04/16/2021	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee