Fasenra (benralizumab)
PAM – 032

Iowa Medicaid Program	Prior Authorization	**Effective Date**	07/01/2021
Revision Number	5	**Last Reviewed**	07/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	07/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	04/16/2021

Overview

Medication: [1]	benralizumab
Brand Name:	Fasenra®
Pharmacologic Category:	Respiratory Tract/Pulmonary Agents; Immunomodulators; Interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa)
FDA-Approved Indication(s):	1. Add-on maintenance treatment of patients with severe asthma 6 years of age and older, and with an eosinophilic phenotype Limitations of Use: • Not indicated for relief of acute bronchospasm or status asthmaticus 2. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA) ▶ **NEW** indication (FDA-approved 9/17/2024)
How Supplied:	Single-dose prefilled syringe, 30 mg/mL Single-dose autoinjector, 30 mg/mL
Dosage 1. Add-on maintenance treatment of severe asthma a. Adult and adolescent patients 12 years of age and older i. 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter b. Pediatric patients 6 to 11 years of age i. **Less than 35 kg:** 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter ii. **5 kg or more:** 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter 2. Eosinophilic granulomatosis with polyangiitis (EGPA) in adult patients a. 30 mg (one injection) administered subcutaneously once every 4 weeks Administration • Prefilled syringe is intended for administration by a healthcare provider • Autoinjector (Fasenra Pen™) is intended for administration by patients/caregivers (patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate). ○ In patients 6 to 11 years of age weighing 35 kg or more, Fasenra Pen™ should only be administered by a caregiver or healthcare provider.	
Benefit Category:	Medical

Descriptive Narrative

Asthma

The following definition for asthma was reached by consensus of the Global Initiative for Asthma (GINA), based on consideration of the characteristics that are typical of asthma before ICS-containing treatment is started, and that distinguish it from other respiratory conditions. However, airflow limitation may become persistent later in the course of the disease.

- Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms, such as wheeze, shortness of breath, chest tightness, and cough, that vary over time and in intensity, together with variable expiratory flow.[2]

Asthma is usually associated with airway hyperresponsiveness and airway inflammation, but these are not necessary or sufficient to make the diagnosis. The diagnosis of asthma is based on the history of characteristic symptom patterns and evidence of variable expiratory flow.

Severe asthma affects 5 to 10 percent of the asthma population but drives the majority of the morbidity and costs of the disease. It 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]

Notably, severe asthma is not determined based on the severity of untreated symptoms or exacerbations. Even patients with highly symptomatic or life-threatening asthma when untreated can usually achieve good asthma control with standard controller therapies.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Several conditions share a symptom complex and can be confused with severe asthma. In addition, some conditions may accompany asthma and cause it to appear more severe or less responsive to therapy. One of these conditions is eosinophilic granulomatosis with polyangiitis (EGPA).

EGPA is one type of a disease known as the antineutrophil cytoplasmic antibody (ANCA)-associated vasculitides (AAV). These diseases affect small- and medium-sized vessels and are characterized by multisystem organ involvement. The vasculitis in EGPA, when present, may be difficult to diagnose depending on the ability to obtain biopsies off treatment or in locations where affected vessels can be obtained.

Asthma is the cardinal clinical feature of EGPA, present in more than 90 percent of patients, and usually precedes vasculitis by approximately 8 to 10 years. Other common symptoms include nasal and sinus symptoms, and peripheral neuropathy. Other than the allergic manifestations, the most commonly involved organs are the lungs, the skin, and the peripheral nervous system. However, EGPA can affect almost any organ system, including the cardiovascular, gastrointestinal, kidney, and central nervous systems. Vasculitis of extrapulmonary organs can result in significant morbidity and mortality.

Historically, the clinical features of EGPA have been described as occurring in sequential phases. In practice, however, these phases are not always distinguishable, and some patients present acutely with vasculitis.

Sequential Phases of EGPA Clinical Features (phases not always distinguishable)

• **Prodromal phase**	This designation, typically applied retrospectively to patients diagnosed with EGPA, describes the development of adult-onset atopic disease, including allergic rhinitis, asthma, and chronic rhinosinusitis (with or without polyposis). This phase may precede or occur simultaneously with the observation of peripheral blood eosinophilia.
• **Eosinophilic phase –**	In the absence of systemic glucocorticoids or anti-eosinophilic biologic therapy for asthma treatment, most patients with EGPA develop significant peripheral blood eosinophilia and eosinophilic infiltration of affected organs, such as the lung and gastrointestinal tract. For example, in one case series, 97 percent of patients presented with blood eosinophil counts ≥500 cells/microL (mean 7,500 ± 6,428 cells/microL) regardless of ANCA status.
• **Vasculitic phase –**	Clinically apparent vasculitis is characterized by the development of organ- or life-threatening systemic vasculitis of the medium and small vessels. Biopsies of affected organs may show vascular and extravascular granulomatosis or perivascular eosinophils. The vasculitic phase may be heralded by nonspecific constitutional symptoms and signs, especially fever, weight loss, and malaise.

Treatment approach to patients with EGPA depends in part on whether the patient has developed organ- or life-threatening manifestations (severe EGPA) or has less severe disease. Patients with non-severe disease have no organ-threatening or life-threatening manifestations. They most frequently present with a combination of rhinosinusitis, asthma, mild systemic symptoms, rash, and/or inflammatory arthritis. Patients with non-severe disease are frequently still very symptomatic, however, particularly with respect to asthma and sinus symptoms.[4]

Guidelines

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2025) proposes a step-wise approach to **asthma** treatment. Fasenra® is listed as an option for add-on therapy in patients 12 years of age and older with severe eosinophilic asthma. Severe asthma is defined as asthma that is uncontrolled despite adherence to optimized high-dose ICS/LABA therapy or that worsens when high-dose treatment is decreased.[5] Of note, guidelines have not been updated since the lower age indication of Fasenra® was FDA-approved.

The goal of therapy in patients with **eosinophilic granulomatosis with polyangiitis (EGPA)** is to achieve long-term quiescence of active disease (remission) in all organ systems. The American College of Rheumatology/ Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated (ANCA) Vasculitis (2021) includes recommendations regarding the management of EGPA. Of note, these recommendations do not specifically mention Fasenra™ (as article was published in 2021) but they do make note of another anti-IL-5 agent (mepolizumab) as an agent that can be used in non-severe disease as part of the remission induction therapy. [6]

For patients with active, non-severe EGPA (i.e., no life- or organ-threatening manifestations), glucocorticoids (in moderate to high doses) are a mainstay of induction therapy. For those unable to achieve remission or who have an early relapse on glucocorticoid therapy, the addition of an anti-IL-5/5R agent is recommended (anti-eosinophilic biologic therapy). Patients with non-severe disease who do not develop remission despite treatment with high-dose glucocorticoids and anti-IL-5/5R therapy may require cyclophosphamide- or rituximab-based regimens like those with organ-threatening disease.

For patients who present with severe disease, induction therapy with both high-dose intravenous glucocorticoids and either cyclophosphamide or rituximab is recommended, rather than glucocorticoids alone. It is also recommended to start an anti-IL-5/5R to reduce eosinophils as early as possible to help minimize side effects and toxicity from induction agents.

The choice between cyclophosphamide and rituximab depends on organ manifestations, side-effect profile, and availability.[7]

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 patients 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.

Eosinophilic Asthma

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 and/or b):
   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 6 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. Request meets one of the following (a, b, c, or d):
   a. Member is 6 to 11 years of age and weighs less than 35 kg: dose does not exceed 10 mg every 4 weeks for the first 3 doses, then 10 mg every 8 weeks thereafter; or
   b. Member is 6 to 11 years of age and weighs 35 kg or more: dose does not exceed 30 mg every 4 weeks for the first 3 doses, then 30 mg every 8 weeks thereafter; or
   c. Member is 12 years of age or older: dose does not exceed 30 mg every 4 weeks for the first 3 doses, then 30 mg every 8 weeks thereafter; or
   d. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Fasenra® is considered medically necessary for continuation of therapy [for asthma] 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. Request meets one of the following (a, b, c, or d):
    a. Member is 6 to 11 years of age and weighs less than 35 kg: dose does not exceed 10 mg every 8 weeks; or
    b. Member is 6 to 11 years of age and weighs 35 kg or more: dose does not exceed 30 mg every 8 weeks; or
    c. Member is 12 years of age or older: dose does not exceed 30 mg every 8 weeks; or
    d. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

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

1. Diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and **ONE** of the following is met (a or b):
    a. Member has active, non-severe disease; **OR**
    b. Member has severe disease and Fasenra® is not used as monotherapy; **AND**
2. Member is 18 years of age or older; **AND**
3. If member has non-severe disease, is currently receiving a systemic corticosteroid (e.g., prednisone) and has been on therapy for a minimum of 4 weeks; **AND**
4. Member has an absolute eosinophil count (AEC) that meets at least one of the following (a and/or b):
    a. 150 cells/mcL or higher within the past 6 weeks; and/or
    b. 150 cells/mcL prior to treatment with another monoclonal antibody therapy that may alter blood eosinophil levels (e.g., Cinqair, Dupixent, Nucala, Tezspire, etc.); **AND**

5. Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or rheumatologist; **AND**
6. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 30 mg once every 4 weeks; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Fasenra® is considered medically necessary for continuation of therapy [for eosinophilic granulomatosis with polyangiitis (EGPA)] 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 positive clinical response to therapy, as determined by prescribing provider (e.g., reduced rate of relapse, corticosteroid dose reduction, reduced eosinophil levels); **AND**
3. Prescribed by, or in consultation with, an allergist, immunologist, pulmonologist, or rheumatologist; **AND**
4. Request meets one of the following (a or b):
    a. Regimen prescribed does not exceed 30 mg once every 4 weeks; or
    b. Regimen is supported by clinical practice guidelines. Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

	Quantity Limits		Approval Duration	
Asthma	Initial Authorization	Subsequent	Initial	Subsequent
6 to 11 years of age, weight < 35 kg	10 mg every 4 weeks for 3 doses, then 10 mg every 8 weeks	10 mg every 8 weeks	6 months	12 months
6 to 11 years of age, weight 35 kg or more	30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks	30 mg every 8 weeks		
12 years of age or older	30 mg every 4 weeks for 3 doses, then 30 mg every 8 weeks	30 mg every 8 weeks		
EGPA	Initial Authorization	Subsequent	Initial	Subsequent
Adult (18 years of age or older)	30 mg every 4 weeks	30 mg every 4 weeks	6 months	12 months

EGPA: eosinophilic granulomatosis with polyangiitis

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
J82.83	Eosinophilic asthma
M30.1	Eosinophilic granulomatosis with polyangiitis [EGPA]

NDC	Strength	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
00310-1730-30	Single-dose prefilled syringe, 30 mg/mL [Fasenra®]	AstraZeneca Pharmaceuticals LP	1 mg	1	EA	30
00310-1745-01	Single-dose prefilled syringe, 10 mg/0.5 mL [Fasenra®]	AstraZeneca Pharmaceuticals LP	1 mg	1	EA	10
00310-1830-30	Single-dose auto-injector, 30 mg/mL [Fasenra Pen®]	AstraZeneca Pharmaceuticals LP	1 mg	1	EA	30

Compliance

1. Should conflict exist between the 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 (09/2024). AstraZeneca Pharmaceuticals LP: Wilmington, DE. Available online: www.fasenrahcp.com. Accessed June 9, 2025.

[2] Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org.

[3] Sharma S, Carr TF. Evaluation of severe asthma in adolescents and adults. Dieffenbach P, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[4] Khoury P. Clinical features and diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA). Dieffenbach P, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

[5] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org.

[6] Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Rheumatol. 2021 Aug;73(8):1366-1383. Epub 2021 Jul 8. PMID: 34235894.

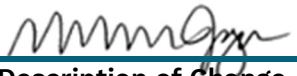
[7] Khoury P. Eosinophilic granulomatosis with polyangiitis (EGPA): Treatment and Prognosis. Dieffenbach P, ed. UpToDate. Waltham, MA: UpToDate Inc. www.uptodate.com. Accessed June 9, 2025.

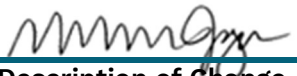
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published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

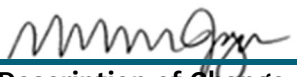
Criteria Change History

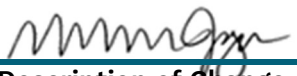
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

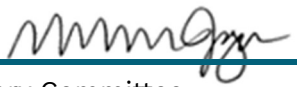
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC	Annual review. Updated Overview, Descriptive Narrative, and Criteria to include new indication for coverage of eosinophilic granulomatosis with polyangiitis (EGPA) in adults (FDA-approved 9/17/2024). Added a "Guidelines" section and included current recommendations for treatment of asthma and EGPA. Updated Approval Duration and Quantity Limits, Coding and Product Information, and References.	5
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Annual review. Updated Overview table with revised indication, including dosing information (approved 4/5/2024 for use in patients 6 years and older). Adjusted age requirements and added dosing information in criteria. Updated Guidelines section with "2020 Focused Updates to the Asthma Management Guidelines." Updated Approval Duration and Quantity Limits, Coding and Product Information, and references.	4
Signature William (Bill) Jagiello, DO			

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