CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Immunologicals – Fasenra Utilization Management Medical Policy
- Fasenra® (benralizumab subcutaneous injection – AstraZeneca)

REVIEW DATE: 04/22/2026; selected revision 04/29/2026

OVERVIEW

Fasenra, an interleukin-5 receptor alpha (IL-5Rα)-directed cytolytic monoclonal antibody, is indicated for the following uses:[1]

- **Asthma** as add-on maintenance treatment of patients ≥ 6 years of age with severe disease and an eosinophilic phenotype. Limitations of Use: Fasenra is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm/status asthmaticus.
- **Eosinophilic granulomatosis with polyangiitis** (EGPA) in adults.

Clinical Efficacy

Asthma

In two pivotal asthma studies, the addition of Fasenra to existing therapy significantly reduced annualized asthma exacerbation rates in patients with baseline blood eosinophil levels ≥ 300 cells/microliter.[2-4] The magnitude of the improvements observed with Fasenra in this patient population were larger than those observed in patients with lower baseline eosinophil levels (e.g., < 150 cells/microliter). Another pivotal study involved adults with severe asthma receiving high-dose inhaled corticosteroid (ICS)/long-acting beta$_2$-agonist (LABA) and chronic oral corticosteroid therapy who had a baseline blood eosinophil level ≥ 150 cells/microliter.[4]

Eosinophilic Granulomatosis with Polyangiitis

One study evaluated the efficacy of Fasenra in patients ≥ 18 years of age with relapsing or refractory EGPA who had received ≥ 4 weeks of a stable oral corticosteroid dose (i.e., prednisolone, prednisone, methylprednisolone, or hydrocortisone).[11] The primary endpoint was the proportion of patients in remission at both Week 36 and Week 48.

Dosing Information

Asthma

The recommended dosage in adult and pediatric patients ≥ 12 years of age is 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, then every 8 weeks thereafter.[1] For pediatric patients 6 years to 11 years of age weighing < 35 kg, the recommended dose is 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, then every 8 weeks thereafter. For pediatric patients 6 years to 11 years of age weighing ≥ 35 kg, the recommended dose is 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, then every 8 weeks thereafter.

EGPA

The recommended dosage is 30 mg (one injection) administered subcutaneously once every 4 weeks.[1]

Guidelines

Asthma

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2025) proposes a step-wise approach to asthma treatment.[5] Fasenra is listed as an option for add-on therapy in patients ≥

12 years of age with severe eosinophilic asthma. The recent guideline update did not include the lower age indication of Fasenra. 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. Higher blood eosinophil levels, higher number of severe exacerbations in the previous year, adult-onset asthma, nasal polyps, maintenance oral corticosteroid requirements, and low lung function may predict a good asthma response to Fasenra.

According to the European Respiratory Society/American Thoracic Society guidelines (2014; updated in 2020), severe asthma is defined as asthma which requires treatment with a high-dose ICS in addition to a second controller medication (and/or systemic corticosteroids) to prevent it from becoming uncontrolled, or asthma which remains uncontrolled despite this therapy.[6,7] Uncontrolled asthma is defined as asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids or asthma that meets one of the following four criteria:

1) Poor symptom control: Asthma Control Questionnaire consistently ≥ 1.5 or Asthma Control Test < 20;
2) Frequent severe exacerbations: two or more bursts of systemic corticosteroids in the previous year;
3) Serious exacerbations: at least one hospitalization, intensive care unit stay, or mechanical ventilation in the previous year;
4) Airflow limitation: forced expiratory volume in 1 second (FEV_1) < 80% predicted after appropriate bronchodilator withholding.

Eosinophilic Granulomatosis with Polyangiitis Guidelines

The American College of Rheumatology (ACR)/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated (ANCA) Vasculitis (2021) includes recommendations regarding the management of EGPA.[12] Fasenra is not addressed. However, for patients with active, non-severe EGPA, combination therapy with an anti-IL-5 agent and a corticosteroid is recommended over other traditional treatments such as methotrexate, azathioprine, or mycophenolate mofetil in the setting of remission induction. Non-severe EGPA is defined as vasculitis in the absence of life- or organ-threatening manifestations. In general, the clinical profile includes rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, and mild inflammatory arthritis. An anti-IL-5 agent, in combination with corticosteroids, is also a recommended therapy for patients who have relapsed and are experiencing non-severe disease manifestations (i.e., asthma and/or sinonasal disease) while receiving either low-dose corticosteroids alone, methotrexate, azathioprine, or mycophenolate mofetil. For patients with severe EGPA, cyclophosphamide or rituximab is preferred over an anti-IL-5 agents for remission induction. The European Alliance of Associations for Rheumatology (EULAR) recommendations for the management of ANCA-associated vasculitis (2022) also do not yet address Fasenra.[13] However, similar to the ACR guidelines, EULAR recommends an anti-IL-5 agent for induction of remission in patients with relapsing or refractory EGPA without active organ- or life-threatening disease. It is also recommended for maintenance of remission in these patients. Additionally, it is also among the many recommended treatment options for the maintenance of remission of EGPA after induction of remission for organ-threatening or life-threatening disease.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Fasenra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the durations noted below. In cases where the approval is

authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Fasenra, as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Fasenra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Fasenra is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. Asthma. Approve Fasenra for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 6 years of age; AND

ii. Patient meets ONE of the following (a or b):

a) Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks; OR

b) Patient had a blood eosinophil level ≥ 150 cells per microliter prior to treatment with Fasenra or another monoclonal antibody therapy that may alter blood eosinophil levels; AND

Note: Examples of monoclonal antibody therapies that may alter blood eosinophil levels include Fasenra, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Dupixent (dupilumab subcutaneous injection), Ebglyss (lebrikizumab-lbkz subcutaneous injection), Exdensur (depemokimab-ulaa subcutaneous injection), Nemluvio (nemolizumab-ilto subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

iii. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):

a) An inhaled corticosteroid; AND

b) At least one additional asthma controller or asthma maintenance medication; AND

Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Dupixent, Exdensur, Fasenra, Nucala, Tezspire, Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfill the requirement for both criteria a and b.

iv. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):

Note: "Baseline" is defined as prior to receiving Fasenra or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Fasenra, Cinqair, Dupixent, Exdensur, Nucala, Tezspire, and Xolair.

a) Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR

b) Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; OR

c) Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; OR
d) Patient has an FEV_1/forced vital capacity (FVC) < 0.80; OR
e) Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; AND

v. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; OR

B) Patient is Currently Receiving Fasenra. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):

i. Patient has already received at least 6 months of therapy with Fasenra; AND
Note: A patient who has received < 6 months of therapy or who is restarting therapy with Fasenra should be considered under criterion 1A (Asthma, Initial Therapy).

ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; AND

iii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Fasenra therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department, urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

Dosing. Approve ONE of the following dosing regimens (A, B, or C):

A) For patients ≥ 12 years of age, approve 30 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter; OR

B) For patients 6 years to 11 years of age who weigh < 35 kg, approve 10 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter; OR

C) For patients 6 years to 11 years of age who weigh ≥ 35 kg, approve 30 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter.

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2. Eosinophilic Granulomatosis with Polyangiitis (EGPA) [formerly known as Churg-Strauss Syndrome]. Approve Fasenra for the duration noted if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve for 9 months if the patient meets ALL of the following (i, ii, iii, and iv):

i. Patient is ≥ 18 years of age; AND

ii. Patient has active, non-severe disease; AND
Note: Non-severe disease is defined as vasculitis without life- or organ-threatening manifestations. Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis.

iii. Patient meets BOTH of the following (a and b):

a) Patient is currently receiving a systemic corticosteroid (e.g., prednisone) and has been on therapy for a minimum of 4 weeks; AND

b) Patient meets ONE of the following [(1) or (2)]:

(1) Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 4 weeks; OR

(2) Patient had a blood eosinophil level ≥ 150 cells per microliter prior to treatment with Fasenra or another monoclonal antibody therapy that may alter blood eosinophil levels; AND
Note: Examples of monoclonal antibody therapies that may alter blood eosinophil levels include Fasenra, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair

(reslizumab intravenous infusion), Dupixent (dupilumab subcutaneous injection), Ebglyss (lebrikizumab-lbkz subcutaneous injection), Exdensur (depemokimab-ulaa subcutaneous injection), Nemluvio (nemolizumab-ilto subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

iv. The medication is prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist; OR

B) Patient is Currently Receiving Fasenra. Approve for 1 year if the patient meets BOTH of the following (i and ii):

i. Patient has already received at least 9 months of therapy with Fasenra; AND
Note: A patient who has received < 9 months of therapy or who is restarting therapy with Fasenra should be considered under criterion 2A (Eosinophilic Granulomatosis with Polyangiitis, Initial Therapy).

ii. Patient has responded to therapy as determined by the prescriber.
Note: Examples of a response to Fasenra therapy are reduced rate of relapse, corticosteroid dose reduction, and reduced eosinophil levels.

Dosing. Approve 30 mg administered subcutaneously once every 4 weeks.

Conditions Not Recommended for Approval

Coverage of Fasenra is not recommended in the following situations:

1. **Chronic Obstructive Pulmonary Disease (COPD).** Fasenra is not indicated for the treatment of COPD.[1] One double-blind, placebo-controlled, Phase IIa study (n = 101) evaluated the efficacy and safety of Fasenra in patients 40 to 80 years of age with eosinophilia and moderate to severe COPD.[8] The annualized rate of acute COPD exacerbations was not reduced with Fasenra compared with placebo. Lung function was also not significantly improved with Fasenra vs. placebo. Numerically greater (although non-significant) improvements in exacerbations and lung function were observed with Fasenra vs. placebo in patients with baseline blood eosinophil levels of 200 cells/microliter or more. Two double-blind, placebo-controlled, Phase III studies (GALATHEA and TERRANOVA) also evaluated Fasenra in patients with moderate to very severe COPD (n = 1,120 and n = 1,545 patients, respectively, with eosinophils ≥ 220 cells/mm^3).[9] Following, 56 weeks of therapy, the annualized COPD exacerbation rates were not statistically significantly reduced with Fasenra vs. placebo in either study. Current COPD guidelines from the Global Initiative for Chronic Lung Disease (2026) note the findings of GALATHEA and TERRANOVA and do not provide recommendations for use of Fasenra.[10]

2. **Chronic Spontaneous Urticaria.** Fasenra is not indicated for the treatment of chronic spontaneous urticaria.[1] One double-blind, placebo-controlled, Phase IIb study (ARROYO) [n = 155] evaluated the efficacy and safety of several doses of Fasenra in adults with chronic spontaneous urticaria who were currently receiving H1 antihistamine treatment.[14] Despite near-complete depletion of blood eosinophils, at Week 12, there were no significant differences in the change from baseline in the Itch Severity Score 7 or the Urticaria Activity Score 7 between any of the Fasenra doses and placebo. There were also no differences between Fasenra and placebo for any of the secondary endpoints evaluated.

3. **Concurrent use of Fasenra with another Monoclonal Antibody Therapy.** The efficacy and safety of Fasenra used in combination with other monoclonal antibody therapies have not been established.
Note: Monoclonal antibody therapies are Adbry® (tralokinumab-ldrm subcutaneous injection), Cinqair® (reslizumab intravenous infusion), Dupixent® (dupilumab subcutaneous injection), Ebglyss®

(lebrikizumab-lbkz subcutaneous injection), Exdensur (depemokimab-ulaa subcutaneous injection), Nemluvio® (nemolizumab-ilto subcutaneous injection), Nucala® (mepolizumab subcutaneous injection), Tezspire® (tezepelumab-ekko subcutaneous injection), or Xolair® (omalizumab subcutaneous injection).

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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13. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis*. 2024;83(1):30-47.
14. Altrichter S, Gimenez-Arnau AM, Bernstein JA, et al. Benralizumab does not elicit therapeutic effect in patients with chronic spontaneous urticaria: results from the phase IIb multinational randomized double-blind placebo-controlled ARROYO study. *Br J Dermatol*. 2024;191(2):187-199.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Asthma:** The age of approval was reduced from ≥ 12 years of age to ≥ 6 years of age. Removed leukotriene receptor antagonists as an example of additional asthma controller or asthma maintenance medications. The Dosing criteria were updated to add 10 mg administered subcutaneously (SC) once every 4 weeks for the first three doses or 10 mg administered SC once every 8 weeks for a patient who weighs < 35 kg. The dosing criteria previously in the policy will still apply to a patient who weighs ≥ 35 kg.	04/19/2024

HISTORY (CONTINUED)

Type of Revision	Summary of Changes	Review Date
Selected Revision	**Asthma:** Eosinophil level requirements were clarified to require a level ≥ 150 cells/microliter either within the previous 6 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. **Eosinophilic Granulomatosis with Polyangiitis:** New approval criteria for this indication were added. Initial approval criteria include an age requirement, a requirement that the patient's disease be active and non-severe, a trial of a systemic corticosteroid, an eosinophil level requirement, and specialist involvement. Throughout the policy, Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) were added to notes as examples of monoclonal antibody therapies.	10/02/2024
Annual Revision	**Conditions Not Recommended for Approval:** Chronic spontaneous urticaria was added as a Condition Not Recommended for Approval.	04/09/2025
Annual Revision	**Conditions Not Recommended for Approval:** Hypereosinophilic syndrome was removed as a Condition Not Recommended for Approval. Throughout the policy, Exdensur (depemokimab-ulaa subcutaneous injection) was added to notes as an example of monoclonal antibody therapy.	04/22/2026
Selected Revision	**Asthma:** The dosing regimens were updated from if the patient weighs < 35 kg, approve either 10 mg administered subcutaneously once every 4 weeks for the first 3 doses or 10 mg administered subcutaneously once every 8 weeks OR if the patient weighs ≥ 35 kg, approve either 30 mg administered subcutaneously once every 4 weeks for the first 3 doses or 30 mg administered subcutaneously once every 8 weeks to one of the following 3 dosing options: 1) for patients ≥ 12 years of age, approve 30 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter; 2) for patients 6 years to 11 years of age who weigh < 35 kg, approve 10 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter; or 3) for patients 6 years to 11 years of age who weigh ≥ 35 kg, approve 30 mg administered subcutaneously once every 4 weeks for the first 3 doses, then every 8 weeks thereafter.	04/29/2026