UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2175-10
Program	Prior Authorization/Medical Necessity
Medications	*Fasenra™ (benralizumab) *This program applies to the prefilled autoinjector formulation.
P&T Approval Date	10/2019, 4/2020, 4/2021, 6/2021, 11/2021, 2/2022, 2/2023, 7/2023, 7/2024, 7/2025
Effective Date	10/1/2025

1. Background:

Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype; and for treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

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

2. Coverage Criteria[a]:

A. Severe Asthma

1. Initial Authorization

a. **Fasenra** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of severe asthma

-AND-

(b) Documentation of positive clinical response to Fasenra therapy as demonstrated by at least **one** of the following:

i. Reduction in the frequency of exacerbations
ii. Decreased utilization of rescue medications
iii. Increase in percent predicted FEV1 from pretreatment baseline
iv. Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
v. Reduction in oral corticosteroid requirements

-AND-

(c) Fasenra is being used in combination with an inhaled corticosteroid (ICS)-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

(d) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(e) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist
iii. Pulmonologist

-OR-

(2) **All** of the following:

(a) Diagnosis of severe asthma

-AND-

(b) Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following

i. Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
ii. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
iii. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
iv. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])

v. Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(c) Submission of medical records (e.g., chart notes, laboratory values, etc.) confirming asthma is an eosinophilic phenotype as defined by a baseline (pre-treatment) peripheral blood eosinophil level ≥ 150 cells/µL

-AND-

(d) Fasenra will be used in combination with **one** of the following:

i. **One** maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

ii. Combination therapy including **both** of the following:

- **One** maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

- **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

-AND-

(e) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(f) Prescribed by **one** of the following:

i. Allergist
ii. Immunologist

iii. Pulmonologist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Fasenra** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Fasenra therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency of exacerbations
(b) Decreased utilization of rescue medications
(c) Increase in percent predicted FEV1 from pretreatment baseline
(d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
(e) Reduction in oral corticosteroid requirements

-AND-

(2) Fasenra is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

(3) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

(a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

1. Initial Authorization

a. **Fasenra** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Patient has been established on therapy with Fasenra under an active UnitedHealthcare medical benefit prior authorization for the treatment of EGPA

-AND-

(b) Documentation of positive clinical response to Fasenra therapy as demonstrated by at least **one** of the following:

i. Reduction in the frequency and/or severity of relapses
ii. Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
iii. Disease remission
iv. Reduction in severity or frequency of EGPA-related symptoms

-AND-

(c) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(d) Prescribed by **one** of the following:

i. Pulmonologist
ii. Rheumatologist
iii. Allergist
iv. Immunologist

-OR-

(2) **All** of the following:

(a) Diagnosis of relapsing or refractory EGPA as defined by **all** of the following:

i. Diagnosis of EGPA

-AND-

ii. Past medical history or presence of asthma

-AND-

iii. Presence of at least **two** of the following characteristics typical of EGPA:

- Histopathological evidence of:
  - Eosinophilic vasculitis
  - Perivascular eosinophilic infiltration
  - Eosinophil-rich granulomatous inflammation
- Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
- Pulmonary infiltrates, non-fixed
- Sino-nasal abnormality
- Cardiomyopathy (established by echocardiography or MRI)
- Glomerulonephritis (hematuria, red cell casts, proteinuria)
- Alveolar hemorrhage
- Palpable purpura
- Anti-neutrophil cytoplasmic antibody (ANCA) positive

-AND-

(b) History of relapsing or refractory disease defined as **one** of the following:

i. Relapsing disease as defined as a past history (within the past 2 years) of at least one EGPA relapse (requiring additional or dose escalation of corticosteroids or immunosuppressant, or hospitalization)
ii. Refractory disease as defined as failure to attain remission within the prior 6 months following induction treatment with standard therapy regimens

-AND-

(c) Patient is currently taking standard therapy [i.e., systemic glucocorticoids (e.g., prednisone, methylprednisolone) with or without immunosuppressive therapy (e.g., cyclophosphamide, rituximab)]

-AND-

(d) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

i. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
ii. Anti-IgE therapy [e.g., Xolair (omalizumab)]
iii. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
iv. Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(e) Prescribed by **one** of the following:

i. Pulmonologist
ii. Rheumatologist
iii. Allergist

iv. Immunologist

Authorization will be issued for 12 months.

2. Reauthorization

a. **Fasenra** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to Fasenra therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency and/or severity of relapses
(b) Reduction or discontinuation of doses of corticosteroids and/or immunosuppressant
(c) Disease remission
(d) Reduction in severity or frequency of EGPA-related symptoms

-AND-

(2) Patient is not receiving Fasenra in combination with **any** of the following for treatment of the same indication:

(a) Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]
(d) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limitations may be in place.
- Medical Necessity may be in place.
- The prefilled syringe is typically covered under the medical benefit. Please refer to the United Healthcare Medical Benefit Drug Policy: "Respiratory Interleukins (Cinqair®, Fasenra®, and Nucala®)".

4. References:

1. Fasenra [prescribing information]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; September 2024.
2. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J.* 2014 Feb:43(2):343-73.
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4. Centers for Disease Control and Prevention. Asthma. Available at http://www.cdc.gov. Accessed June 2025.
5. National Heart, Lung and Blood Institute. Asthma Management Guidelines. Available at http://www.nhlbi.nih.gov. Accessed June 2025.
6. FitzGerald JM, Bleecker ER, Menzies-Gow A, et al. Predictors of enhanced response with benralizumab for patients with severe asthma: pooled analysis of the SIROCCO and CALIMA studies. Lancet Respir Med. 2017 Sep 8.
7. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613.
8. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588. doi: 10.1183/13993003.00588-2019. PMID: 31558662

Program	Prior Authorization/Medical Necessity - Fasenra (benralizumab)
Change Control	
10/2019	New program.
4/2020	Updated program to address specific product formulations. Updated references.
4/2021	Annual review. No changes to clinical criteria. Added limitations of use. Updated references.
6/2021	Added criteria if patient has been approved and received initial dose of Fasenra directly monitored by a healthcare professional without reaction.
11/2021	Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit. Removed prescriber requirement for reauthorization.
2/2022	Added Tezspire to list of agents not to be used in combination with Fasenra and updated formatting of prescriber requirement.
2/2023	Annual review with no updates to coverage criteria. Updated references.
7/2023	Updated coverage criteria for severe asthma to align with GINA & ERS/ATS guidelines. Added/updated examples of ICS-containing maintenance medications, removed requirement that peripheral blood eosinophil level must be within 6 weeks, and removed bypass of eosinophilic phenotype requirement for patients currently dependent on maintenance therapy with oral corticosteroids. Updated references.

7/2024	Annual review. Modified criteria for existing prior authorization for under the medical benefit. Updated background for expanded indication for ages 6 years and older. Updated references.
7/2025	Annual review. Added new indication and criteria for EGPA. Updated statement for concomitant use. Updated background and references.