UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1299-8
Program	Prior Authorization/Notification
Medications	*Fasenra® (benralizumab) *This program applies to the prefilled autoinjector formulation.
P&T Approval Date	10/2019, 4/2020, 4/2021, 11/2021, 11/2022, 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

-AND-

(c) Fasenra will be used in combination with maintenance therapy [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:

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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 therapy [e.g., Tezspire (tezepelumab)]

-OR-

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

(a) Diagnosis of severe asthma

-AND-

(b) Fasenra will be used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

(c) Asthma is an eosinophilic phenotype

-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 therapy [e.g., Tezspire (tezepelumab)]

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

-AND-

(2) Fasenra will be used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone

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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 therapy [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

-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 therapy [e.g., Tezspire (tezepelumab)]

-OR-

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

(a) Diagnosis of EGPA

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-AND-

(b) 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 therapy [e.g., Tezspire (tezepelumab)]

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

-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 therapy [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®)".

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4. References:

1. Fasenra [prescribing information]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; September 2024.

Program	Prior Authorization/Notification - 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.
11/2021	Added coverage criteria for patients established on therapy under UnitedHealthcare medical benefit.
11/2022	Annual review with no changes to coverage criteria. Added state mandate footnote and updated references.
7/2023	Updated required diagnosis to "severe asthma". Added examples of maintenance therapy. Added Tezspire to list of agents that should not be used in combination with Fasenra. Removed bypass of eosinophilic phenotype requirement for patients currently dependent on maintenance therapy with oral corticosteroids to align with label.
7/2024	Annual review. Updated background for ages 6 years and older. Modified criteria for existing prior authorization for under the medical benefit. Updated reference.
7/2025	Annual review. Added indication and criteria for EGPA. Updated statement for concomitant use. Updated background and reference.

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