UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Fasenra

Program	Prior Authorization
Medication	Fasenra Pen™ (benralizumab)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	12/2019
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

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 12 years and older, and with an eosinophilic phenotype.

2. Coverage Criteria:

A. Severe Asthma

1. Initial Authorization

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

(1) Diagnosis of severe asthma

-AND-

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

(a) 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)
(b) Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months

(c) Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
(d) 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])
(e) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(3) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting **one** of the following:

(a) Asthma is an eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/μL within the past 6 weeks

-OR-

(b) Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma

-AND-

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

(a) **One** high dose (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-

(b) Combination therapy including **both** of the following:

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

-AND-

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

-AND-

(5) Patient is not receiving Fasenra in combination with **any** of the following:

(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)]

-AND-

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

(a) Pulmonologist
(b) Allergist
(c) Immunologist

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 controller medication

-AND-

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

(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)]

-AND-

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

(a) Pulmonologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- 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 limits may be in place.

4. References:

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; October 2019.
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.
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available at http://www.ginasthma.org. Accessed June 2019.
4. Centers for Disease Control and Prevention. Asthma. Available at http://www.cdc.gov. Accessed June 2019.
5. National Heart, Lung and Blood Institute. Explore Asthma. Available at http://www.nhlbi.nih.gov. Accessed May 2016.

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.

Program	Prior Authorization
Change Control	
Date	Change
12/2020	Annual review. No changes to clinical criteria. Minor formatting changes in reference section.
12/2019	New program