SmartHealth

Ascension

Benralizumab

(Fasenra®) J0517

Covered with prior authorization

Benralizumab (Fasenra®) may be authorized when the following criteria are met:

- Diagnosis of severe eosinophilic asthma; **AND**
- Individuals aged 12 years or older; **AND**
- Severe asthma uncontrolled by medium-high dosage inhaled corticosteroids plus long-acting B2-agonists (ICS+LABA); **AND**
- History of 2+ exacerbations in the previous 12 months; **AND**
- Dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter**.**

Exclusion criteria:

- Pediatric individuals age <12 years;
- Hypersensitivity to benralizumab or any component of the formulation;
- Individuals with other eosinophilic conditions (non asthma);
- Not for the relief of acute bronchospasm or status asthmaticus;
- Will not be used in combination with another antiasthmatic monoclonal antibody (for example, Cinqair, Nucala, Xolair);
- Individuals with known parasitic (helminth) infections;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.

Initial authorization is up to 12 months.

Continuation requests may be approved if there is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of the disease. Clinical documentation provided must be from within the most recent 12 months.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage

FASENRA® is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1, kappa) indicated

- for the add-on maintenance treatment of individuals with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

References:

Developed by: Medical Specialty Prior Authorization Team, April 2022
Approved by: Ambulatory Care Expert Review Panel, April 2022; Therapeutic Affinity Group, May 2022

Ascension. (2022, January). *Medical Specialty Respiratory Drug Review for SmartHealth: SBAR*. Ascension TAG INITIATIVES - PSWP.
Ascension. (2022, January 21). *Benralizumab (Fasenra) Criteria for Use*. Ascension TAG INITIATIVES - PSWP.
Fasenra® (benralizumab) label. (2017, December). Accessdata.fda.gov. Retrieved April 23, 2022, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761070s000lbl.pdf
Fasenra® (benralizumab) [prescribing information] Wilmington, DE: AstraZeneca; 10/2019
FitzGerald M, Bleecker E, Nair P, *et al*. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for individuals with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blind, placebo-controlled phase 3 trial. *Lancet* 2016;388:2128-41

Criteria History/ Revision Information:

Date	Summary of Changes
January 2022	Medical Specialty Respiratory Drug Review for SmartHealth SBAR developed by Ambulatory Care Expert REview Panel
January 2022	Approved by Ambulatory Care Steering Committee
February 2022	Approved by Therapeutic Affinity Group
April 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
May 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.