# Clinical Policy: Benralizumab (Fasenra)

Reference Number: CP.PHAR.373
Effective Date: 01.16.18
Last Review Date: 05.18
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

## Description

Benralizumab (Fasenra™) is an interleukin (IL)-5 receptor alpha-directed cytolytic monoclonal antibody.

## FDA Approved Indication(s)

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

Limitation(s) of use:

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

## Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation® that Fasenra is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Severe Asthma** (must meet all)**:**

1. Diagnosis of asthma with absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;
2. Prescribed by or in consultation with a pulmonologist or allergist;
3. Age ≥ 12 years;
4. Member has experienced ≥ 2 exacerbations within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., high-dose inhaled corticosteroid (ICS) plus either a long-acting beta$_2$ agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindication/intolerance):
   a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
   b. Urgent care visit or hospital admission;
   c. Intubation;
5. Fasenra is prescribed concomitantly with an ICS plus either a LABA or LTRA;
6. Dose does not exceed 30 mg every 4 weeks for the first 3 doses, then 30 mg every 8 weeks thereafter.

**Approval duration: 6 months**

**B. Other diagnoses/indications**
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

## II. Continued Therapy

**A. Severe Asthma** (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either a LABA or LTRA;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 30 mg every 8 weeks.

**Approval duration:**
**Medicaid** – 12 months
**Commercial** – 6 months or member's renewal period, whichever is longer

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;

**B.** Acute bronchospasm or status asthmaticus.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

| | |
|---|---|
| FDA: Food and Drug Administration | IL: interleukin |
| BEC: blood eosinophil count | LABA: long-acting beta$_2$ agonist |
| ICS: inhaled corticosteroid | LTRA: leukotriene modifier |

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **ICS** | | |
| Qvar® (beclomethasone) | 40 mcg, 80 mcg per actuation<br>1-4 actuations BID | 4 actuations BID |
| budesonide (Pulmicort®) | 90 mcg, 180 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Alvesco® (ciclesonide) | 80 mcg, 160 mcg per actuation<br>1-2 actuations BID | 2 actuations BID |
| Aerospan® (flunisolide) | 80 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Flovent® (fluticasone propionate) | 44-250 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Arnuity Ellipta® (fluticasone furoate) | 100 mcg, 200 mcg per actuation<br>1 actuation QD | 1 actuation QD |
| Asmanex® (mometasone) | HFA: 100 mcg, 200 mcg per actuation<br>Twisthaler: 110 mcg, 220 mcg per actuation<br>1-2 actuations QD to BID | 2 inhalations BID |
| **LABA** | | |
| Serevent® (salmeterol) | 50 mcg per dose<br>1 inhalation BID | 1 inhalation BID |
| **Combination products (ICS + LABA)** | | |
| Dulera® (mometasone/ formoterol) | 100/5 mcg, 200/5 mcg per actuation<br>2 actuations BID | 4 actuations per day |
| Breo Ellipta® (fluticasone/vilanterol) | 100/25 mcg, 200/25 mcg per actuation<br>1 actuation QD | 1 actuation QD |
| Advair® (fluticasone/ salmeterol) | Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation<br>HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation<br>1 actuation BID | 1 actuation BID |
| fluticasone/salmeterol (Airduo RespiClick®) | 55/13 mcg, 113/14 mcg, 232/14 mcg per actuation<br>1 actuation BID | 1 actuation BID |
| Symbicort® (budesonide/ formoterol) | 80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation<br>2 actuations BID | 2 actuations BID |
| **LTRA** | | |
| montelukast (Singulair®) | 4 to 10 mg PO QD | 10 mg per day |
| zafirlukast (Accolate®) | 10 to 20 mg PO BID | 40 mg per day |
| zileuton ER (Zyflo® CR) | 1200 mg PO BID | 2400 mg per day |
| Zyflo® (zileuton) | 600 mg PO QID | 2400 mg per day |
| **Oral corticosteroids** | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| dexamethasone (Decadron®) | 0.75 to 9 mg/day PO in 2 to 4 divided doses | Varies |
| methylprednisolone (Medrol®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |
| prednisolone (Millipred®, Orapred ODT®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |
| prednisone (Deltasone®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: General Information*

- The pivotal trials defined severe asthma as 2 or more exacerbations of asthma despite regular use of high-dose ICS plus an additional controller (e.g., LABA or LTRA) with or without oral corticosteroids. Although the CALIMA trial included patients receiving medium-dose ICS, Fasenra was not shown to have an effect on annual exacerbation rate, pre-bronchodilator forced expiratory volume in 1 second, or total asthma symptom score in those patients.
- Clinically significant exacerbation was defined as a worsening of asthma (any new or increased symptoms or signs that were concerning) that led to one of the following: (1) use of systemic corticosteroids, (2) emergency department or visit to urgent care center, or (3) inpatient hospital stay.
- Baseline blood eosinophil count (BEC) is a predictor of response to therapy. Although the SIROCCO and CALIMA trials were powered for efficacy analysis in patients with baseline BEC ≥ 300 cells/µL, a pooled analysis which stratified patients by baseline BEC (≥ 0 cells/µL, ≥ 150 cells/µL, ≥ 300 cells/µL, and ≥ 450 cells/µL) found Fasenra to have a statistically significant positive treatment effect on those with baseline BEC ≥ 150 cells/µL. In addition, the ZONDA trial found Fasenra to significantly reduce oral corticosteroid dose in patients with baseline BEC ≥ 150 cells/µL.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Severe asthma | 30 mg SC every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter | See regimen |

## VI. Product Availability

Single-dose prefilled syringe with solution for injection: 30 mg/mL

## VII. References

1. Fasenra Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2017. Available at: www.fasenra.com. Accessed November 20, 2017.
2. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed December 7, 2017.

3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology.com. Accessed November 2017.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 01.16.18 | 05.18 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

**Note:**
**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.