

Clinical Policy: Benralizumab (Fasenra)

Reference Number: CP.PHAR.373

Effective Date: 06.01.18

Last Review Date: 02.22

Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Benralizumab (Fasenra[®]) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgG1 kappa).

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;
2. Member has an absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;
3. Prescribed by or in consultation with a pulmonologist, immunologist, or allergist;
4. Age ≥ 12 years;
5. Member has experienced ≥ 2 exacerbations within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long-acting beta₂ 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;
6. Fasenra is prescribed concurrently with an ICS plus either a LABA or LTRA;
7. Fasenra is not prescribed concurrently with Cinqair[®], Nucala[®], Dupixent[®], or Xolair[®];

8. 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, HIM.PA.154 for health insurance marketplace, 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 (an ICS plus either a LABA or LTRA) as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months);
3. Member is responding positively to therapy (examples may include but are not limited to: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy);
4. Fasenra is not prescribed concurrently with Cinqair, Nucala, Dupixent, or Xolair;
5. If request is for a dose increase, new dose does not exceed 30 mg every 8 weeks.

Approval duration:

Medicaid/HIM – 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, HIM.PA.154 for health insurance marketplace, and 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.PA.154 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
BEC: blood eosinophil count
GINA: Global Initiative for Asthma
ICS: inhaled corticosteroid

LABA: long-acting beta₂ agonist
LTRA: leukotriene modifier
PDC: proportion of days covered

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 (medium – high dose) | | |
| Qvar [®] (beclomethasone) | > 200 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID | 4 actuations BID |
| budesonide (Pulmicort [®]) | > 400 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID | 2 actuations BID |
| Alvesco [®] (ciclesonide) | > 160 mcg/day 80 mcg, 160 mcg per actuation 1-2 actuations BID | 2 actuations BID |
| Aerospan [®] (flunisolide) | > 320 mcg/day 80 mcg per actuation 2-4 actuations BID | 2 actuations BID |
| Flovent [®] (fluticasone propionate) | > 250 mcg/day 44-250 mcg per actuation 2-4 actuations BID | 2 actuations BID |
| Arnuity Ellipta [®] (fluticasone furoate) | 200 mcg/day 100 mcg, 200 mcg per actuation 1 actuation QD | 1 actuation QD |
| Asmanex [®] (mometasone) | >220 mcg/day HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID | 2 inhalations BID |
| LABA | | |
| Serevent [®] (salmeterol) | 50 mcg per dose 1 inhalation BID | 1 inhalation BID |
| Combination products (ICS + LABA) | | |
| Dulera [®] (mometasone/formoterol) | 100/5 mcg, 200/5 mcg per actuation 2 actuations BID | 4 actuations per day |
| Breo Ellipta [®] (fluticasone/vilanterol) | 100/25 mcg, 200/25 mcg per actuation 1 actuation QD | 1 actuation QD |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|--|---|-----------------------------|
| Advair [®] (fluticasone/ salmeterol) | Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation BID | 1 actuation BID |
| fluticasone/salmeterol (Airduo RespiClick [®]) | 55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID | 1 actuation BID |
| Symbicort [®] (budesonide/ formoterol) | 80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 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) | 1,200 mg PO BID | 2,400 mg per day |
| Zyflo [®] (zileuton) | 600 mg PO QID | 2,400 mg per day |
| Oral corticosteroids | | |
| 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: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: 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, Fasentra 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/ μ L, a pooled analysis which stratified patients by baseline BEC (≥ 0 cells/ μ L, ≥ 150 cells/ μ L, ≥ 300 cells/ μ L, and ≥ 450 cells/ μ L) found Fasenera to have a statistically significant positive treatment effect on those with baseline BEC ≥ 150 cells/ μ L. In addition, the ZONDA trial found Fasenera to significantly reduce oral corticosteroid dose in patients with baseline BEC ≥ 150 cells/ μ L.
- The Global Initiative for Asthma (GINA) guidelines recommend Fasenera be considered as adjunct therapy for patients 12 years of age and older with exacerbations or poor symptom control despite taking at least high dose ICS/LABA and who have eosinophilic biomarkers or need maintenance oral corticosteroids. Fasenera may also be considered if the patient is uncontrolled on Step 4 treatment (medium dose ICS/LABA).
- Patients could potentially meet asthma criteria for both Xolair and Fasenera, though there is insufficient data to support the combination use of multiple asthma biologics. The combination has not been studied. Approximately 30% of patients in the Nucala MENSA study also were candidates for therapy with Xolair.
- Lab results for blood eosinophil counts can be converted into cells/mcL using the following unit conversion calculator: <https://www.fasenerahcp.com/m/fasenera-eosinophil-calculator.html>.
- PDC is a measure of adherence. PDC is calculated as the sum of days covered in a time frame divided by the number of days in the time frame. To achieve a PDC of 0.8, a member must have received their asthma controller therapy for 144 days out of the last 180 days, or approximately 5 months of the last 6 months.

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
- Single-dose autoinjector Fasenera Pen with solution for injection: 30 mg/mL

VII. References

1. Fasenera Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021. Available at: www.fasenera.com. Accessed September 23, 2021.
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 September 21, 2021.
3. Cloutler MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults 2020: asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020; 324: 2301-2317.
4. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology.com>. Accessed September 24, 2021.

5. Global Initiative for Asthma. Global strategy for asthma management and prevention (2021 report). Available from: www.ginasthma.org. Accessed September 21, 2021.
6. Global Initiative for Asthma. Difficult-to-treat and severe asthma in adolescent and adult patients – diagnosis and management, v3.0 April 2021. Available at: www.ginasthma.org. Accessed September 22, 2021.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|-------------|-------------------------------|
| J0517 | Injection, benralizumab, 1 mg |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--|----------|-------------------|
| Policy created | 01.16.18 | 05.18 |
| 1Q 2019 annual review: modified ICS requirement to include medium dose ICS per GINA 2018 recommendations; added option for immunologist prescribing; link to blood eosinophil unit conversion calculator added to Appendix D; references reviewed and updated. | 10.11.18 | 02.19 |
| Added HIM-Medical Benefit line of business. | 05.22.19 | |
| 1Q 2020 annual review: revised HIM-Medical Benefit to HIM line of business; added requirement that Fasentra is not prescribed concurrently with other biologic therapies for asthma; added new autoinjector formulation; references reviewed and updated. | 11.07.19 | 02.20 |
| 1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; HCPCS code updated; references reviewed and updated. | 10.26.20 | 02.21 |
| 1Q 2022 annual review: for continuation criteria, defined adherence as PDC of 0.8; references reviewed and updated. | 09.22.21 | 02.22 |

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.

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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.

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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.

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