

Clinical Policy: Benralizumab (Fasenra)

Reference Number: IL.PHAR.373

Effective Date: 9.29.21

Last Review Date: 1.31.24

Line of Business: 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 severe asthma;
2. Member has an absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;
3. Age ≥ 12 years;
4. Fasenra is prescribed concurrently with an ICS plus either a LABA or LTRA;
5. 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 (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Severe Asthma (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
- ;
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. If request is for a dose increase, new dose does not exceed 30 mg every 8 weeks.

Approval duration:

Medicaid– 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: 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.PMN.53 for Medicaid, or evidence of coverage documents;
- B. Acute bronchospasm or status asthmaticus.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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|------------------------------------|---|
| FDA: Food and Drug Administration | LABA: long-acting beta ₂ agonist |
| BEC: blood eosinophil count | LTRA: leukotriene modifier |
| GINA: Global Initiative for Asthma | PDC: proportion of days covered |
| ICS: inhaled corticosteroid | |

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	2 inhalations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	1-2 actuations QD to 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
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, 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/ 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 Fasenra to have a statistically significant positive treatment effect on those with baseline BEC ≥ 150 cells/ μ L. In addition, the ZONDA trial found Fasenra to significantly reduce oral corticosteroid dose in patients with baseline BEC ≥ 150 cells/ μ L.
- The Global Initiative for Asthma (GINA) guidelines recommend Fasenra 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. Fasenra 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 Fasenra, 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.fasenrahcp.com/m/fasenra-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 Fasenra Pen with solution for injection: 30 mg/mL

VII. References

1. Fasenra Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021. Available at: www.fasenra.com. Accessed October 31, 2022.

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 October 25, 2022.
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.; 2022. Available at: <http://www.clinicalpharmacology.com>. Accessed October 25, 2022.
5. Global Initiative for Asthma. Global strategy for asthma management and prevention (2022 report). Available from: www.ginasthma.org. Accessed October 25, 2022.
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 October 25, 2022.

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
Policy created, adapted from CP.PHAR.373 benralizumab (Fasenra) for HFS PDL.	9.29.21	
4Q2021 – added severe to diagnosis of Asthma	12.9.21	
1Q 2022 annual review: for continuation criteria, defined adherence as PDC of 0.8; references reviewed and updated.	3.14.22	
1Q 2024 Annual Review: Template changes applied to other diagnoses/indications and continued therapy section. References reviewed and updated.	1.31.24	

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.

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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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Benralizumab



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