

Fasenra® (benralizumab) (Subcutaneous)

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I. Length of Authorization

- Initial: 6 months for severe eosinophilic asthma; 12 months for EGPA and all other indications
- Renewal: 12 months for all indications

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- **Severe Eosinophilic Asthma**
 - Load: 30 billable units every 28 days for 3 doses
 - Maintenance: 30 billable units every 56 days
- **Eosinophilic Granulomatosis with Polyangiitis (EGPA)**
 - 30 billable units every 28 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Severe Eosinophilic Asthma † ^{1,2,5,7-9,11,12,16}

- Patient is at least 6 years of age; **AND**
- Prescribed by, or in consultation with, an allergist, pulmonologist, or immunologist; **AND**
- Patient has severe disease; **AND**
- Patient has asthma with an eosinophilic phenotype indicated by blood eosinophils ≥ 150 cells/ μ L; **AND**
- History of ≥ 2 asthma exacerbations requiring treatment with systemic corticosteroids or emergency department visit or hospitalization for treatment of asthma within the past year despite adherent utilization of either an inhaled corticosteroid (ICS) with one (1) additional asthma controller medication or maximally tolerated ICS/long-acting beta agonist (LABA) combination product; **AND**
- Prescriber attests to all of the following:

- Patient adherence to controller medications; **AND**
- Will NOT be used in combination with another targeted immunomodulator product used for asthma

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome †^{1,17}

- Patient is at least 18 years of age; **AND**
- Prescribed by, or in consultation with, a rheumatologist, allergist, pulmonologist, or immunologist
- Patient has a confirmed diagnosis of EGPA§ (aka Churg-Strauss Syndrome); **AND**
- One of the following:
 - Baseline blood eosinophil count > 1000 cells/μL
 - Baseline blood eosinophil count > 10% of the total leukocyte count; **AND**
- Trial of oral corticosteroid therapy (equivalent to prednisone 7.5 mg/day for a minimum of 4 weeks) was ineffective, contraindicated, or not tolerated

† FDA Approved indication(s); ‡ Compendia Recommended Indication(s); Ⓞ Orphan Drug

IV. Renewal Criteria^{1,7,8}

Severe Eosinophilic Asthma

- Diagnosis of eosinophilic asthma; **AND**
- Positive clinical response has been achieved; **AND**
- Will NOT be used in combination with another targeted immunomodulator product used for asthma

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome

- Diagnosis of EGPA; **AND**
- Positive clinical response has been achieved

V. Dosage/Administration¹

Indication	Dose
Severe Eosinophilic Asthma	<p><u>Adults and Adolescent Patients ≥ 12 Years of Age</u></p> <p>Administer 30 mg (one injection) subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter.</p> <p><u>Pediatric Patients 6 to 11 Years of Age (Body Weight Dosing)</u></p> <ul style="list-style-type: none"> • < 35 kg: 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter. • ≥ 35 kg: 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)	Administer 30 mg (one injection) subcutaneously every 4 weeks
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VI. Billing Code/Availability Information

HCPCS Code:

- J0517 – Injection, benralizumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Fasenra 10 mg/0.5 mL single-dose prefilled syringe: 00310-1745-xx
- Fasenra 30 mg/mL single-dose prefilled syringe: 00310-1730-xx
- Fasenra 30 mg/mL single-dose autoinjector FASENRA PEN: 00310-1830-xx

VII. References

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; September 2024. Accessed September 2024.
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7. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. *Eur Respir J* 2014; 43: 343-373.
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13. Bleecker ER, FitzGerald JM, Chanez P, et al; SIROCCO study investigators. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β 2-agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. *Lancet*. 2016 Oct 29;388(10056):2115-2127. doi: 10.1016/S0140-6736(16)31324-1. Epub 2016 Sep 5. PMID: 27609408.
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15. Nair P, Wenzel S, Rabe KF, et al; ZONDA Trial Investigators. Oral Glucocorticoid-Sparing Effect of Benralizumab in Severe Asthma. *N Engl J Med*. 2017 Jun 22;376(25):2448-2458. doi: 10.1056/NEJMoa1703501. Epub 2017 May 22. PMID: 28530840.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J82.81	Eosinophilic pneumonia, NOS
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified
M30.1	Polyarteritis with lung involvement [Churg-Strauss]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used

to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC