Fasenra® (benralizumab)
(Subcutaneous)

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I. Length of Authorization

Coverage is provided for 6 months initially and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Fasenra 10 mg single-dose prefilled syringe
  - Load: 1 syringe every 28 days for 3 doses
  - Maintenance: 1 syringe every 56 days
- Fasenra 30 mg single-dose prefilled syringe
  - Load: 1 syringe every 28 days for 3 doses
  - Maintenance: 1 syringe every 56 days
- Fasenra Pen 30 mg single-dose autoinjector
  - Load: 1 autoinjector every 28 days for 3 doses
  - Maintenance: 1 autoinjector every 56 days

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

- Load: 30 billable units every 28 days for 3 doses
- Maintenance: 30 billable units every 56 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 6 years of age; AND

Universal Criteria [1]

- Will not be used in combination with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., omalizumab, mepolizumab, reslizumab, dupilumab, tezepelumab, etc.); **AND**
- Must NOT be used for either of the following:
    - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
    - Relief of acute bronchospasm or status asthmaticus; **AND**

Severe Asthma † [1,2,5,7-9,11,12]

- Patient must have severe* disease; **AND**
- Patient must have asthma with an eosinophilic phenotype indicated by blood eosinophils ≥150 cells/μL within 6 weeks of dosing; **AND**
- Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
    - Medium to high-dose inhaled corticosteroids; **AND**
    - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers, etc.); **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- Baseline measurement of at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    - Forced expiratory volume in 1 second (FEV_1)

*Components of severity for classifying asthma as severe may include any of the following (not all inclusive):[2,9]
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

† FDA-approved indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1,7,8]

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**

- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: parasitic (helminth) infection, severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash), etc.; **AND**
    - Improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more of the following:
        - Use of systemic corticosteroids
        - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
        - Hospitalizations
        - ER visits
        - Unscheduled visits to healthcare provider; **OR**
    - Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

V. Dosage/Administration [1]

Indication	Dose
Severe Asthma with eosinophilic phenotype	**Adults and Adolescent Patients > 12 Years of Age** Administer 30 mg (one injection) subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter. **Pediatric Patients 6 to 11 Years of Age (Body Weight Dosing)** • < 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. ***NOTE:*** • Fasenra single-dose pre-filled syringe is for administration by a healthcare provider. • Patients ≥ 12 years of age: Fasenra Pen single-dose autoinjector is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate. • Patients aged 6 to 11 years weighing ≥ 35 kg: Fasenra Pen should only be administered by a caregiver or healthcare provider.

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; April 2024. Accessed April 2024.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2019 Update. Available from: http://www.ginasthma.org. Accessed September 2020.
4. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014; 7: 53–65.
5. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. Curr Med Res Opin. 2017 Sep;33(9):1605-1613. Doi: 10.1080/03007995.2017.1347091. Epub 2017 Jul 19.
6. The Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2017. Available from: www.ginasthma.org.
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.
8. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
9. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
10. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed June 2021.
11. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 Update. Available from: http://www.ginasthma.org. Accessed September 2023.
12. Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2023 Update. Available from: http://www.ginasthma.org/2023-gina-main-report. Accessed September 2023.

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 β2-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.
14. FitzGerald JM, Bleecker ER, Nair P, et al; CALIMA study investigators. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet. 2016 Oct 29;388(10056):2128-2141. Doi: 10.1016/S0140-6736(16)31322-8. Epub 2016 Sep 5. PMID: 27609406.
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.

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

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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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