MEDICAL MUTUAL®

Drug Policy

Policy:	**201730-MRx (05-24)**	**Initial Effective Date: 1/21/2017**
Code(s):	**HCPCS J0517**	**Annual Review Date: 10/17/2024**
SUBJECT:	**Fasenra® (benralizumab)**	**Last Revised Date: 10/17/2024**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

I. Length of Authorization

Initial coverage will be provided for 6 months 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
  - 1 syringe every 28 days
- Fasenra Pen 30 mg single-dose autoinjector
  - 1 autoinjector every 28

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

- **Severe 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:

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**
- Will 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 † [1,2,5,7-9,11,12,16]

- Patient is at least 6 years of age; **AND**
- Patient has severe***** disease; **AND**
- Patient has asthma with an eosinophilic phenotype indicated by blood eosinophils ≥150 cells/µL or the patient is dependent on systemic corticosteroids; **AND**
- 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, long-acting muscarinic agent, 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

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome † [1,17]

- Patient is at least 18 years of age; **AND**
- Patient has a confirmed diagnosis of EGPA**§** (aka Churg-Strauss Syndrome); **AND**
- Patient has relapsing or refractory disease; **AND**
- Patient has received prior treatment with oral corticosteroids with or without immunosuppressive therapy; **AND**
- Patient has been on a stable dose of oral corticosteroid therapy for at least 4 weeks prior to starting treatment; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses, etc.)

§Eosinophilic Granulomatosis Polyangiitis (EGPA) defined as all of the following:[17]

- History or presence of asthma
- Blood eosinophil level > 10% or an absolute eosinophil count >1000 cells/mm^3
- Two or more of the following criteria:
  - Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation
  - Neuropathy
  - Pulmonary infiltrates
  - Sinonasal abnormalities
  - Cardiomyopathy
  - Glomerulonephritis
  - Alveolar hemorrhage
  - Palpable purpura

– Antineutrophil Cytoplasmic Antibody (ANCA) positivity

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

IV. Renewal Criteria [1,7,8]

Coverage may be renewed based upon the following criteria:

- 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**

Severe Asthma

- 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)

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

- Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced by one or more of the following:
  - Patient is in remission [defined as Birmingham Vasculitis Activity Score (BVAS)=0 (no active vasculitis) plus prednisolone/prednisone dose ≤7.5 mg/day or equivalent]
  - Decreased frequency in the occurrence of relapses
  - Decrease in the daily oral corticosteroid dose
  - Improvement on a disease activity scoring tool [e.g., Vasculitis Damage Index (VDI), Birmingham Vasculitis Activity Score (BVAS), Forced vital capacity (FVC), Forced Expiratory Volume during first second (FEV1), Asthma Control Questionnaire (6-item version) (ACQ-6), etc.]

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.
Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome	Administer 30 mg (one injection) subcutaneously every 4 weeks

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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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.
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10. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: http://www.ginasthma.org. Accessed June 2021.
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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 β2-agonists

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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,	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	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J0517

Edits and Denials:

Prior approval: Prior approval is required for Fasenra **(HCPCS Cods J0517)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.