MEDICA®

Fasenra® (benralizumab)
(Subcutaneous)

Document Number: MAYO-0347

Last Review Date: 10/28/2019
Date of Origin: 12/12/2017
Dates Reviewed: 12/2017, 03/2018, 06/2018, 10/2018, 11/2019

I. Length of Authorization

Coverage is provided for six months and is eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

Severe Asthma with an eosinophilic phenotype
- Load: 30 mg (30 BU) every 28 days x 3 doses
- Maintenance: 30 mg (30 BU) every 56 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Must not be used in combination with another monoclonal antibody (e.g., mepolizumab, reslizumab, etc.); **AND**

Severe Asthma †

- Patient must be at least 12 years of age; **AND**
- Patient must have severe* disease; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as 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**

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- 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)

*Components of severity for classifying asthma as severe may include any of the following (not all
• 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-labeled indication(s)

IV. Renewal Criteria

- Patient continues to meet the criteria identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: parasitic (helminth) infection, severe hypersensitivity reactions, etc.; **AND**
- Treatment has resulted in clinical benefit:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by 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

Indication	Dose
Severe Asthma with eosinophilic phenotype	30 mg administered subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter.

*Store refrigerated at 2ºC to 8ºC

VI. Billing Code/Availability Information

Jcode:

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

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NDC:

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

VII. References

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; November 2017. Accessed October 2019.
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 2019.
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.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82	Pulmonary eosinophilia, not elsewhere classified

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

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

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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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
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

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