Fasenra® (benralizumab)  
(Subcutaneous)

Last Review Date: 06/1/2018  
Date of Origin: 12/12/2017  
Dates Reviewed: 12/2017, 03/2018, 06/2018

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:
     o Load: 1 syringe every 28 days for 3 doses
     o 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., omalizumab 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:
  o Medium to high-dose inhaled corticosteroids: AND
  o An additional controller medication (e.g., long-acting beta agonist, etc.): AND
- Patient must have ONE of the following:
  o Two or more exacerbations in the previous year: OR
o Require 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 inclusive):

- 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 FEV₁) <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 (FEV₁)

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>Severe Asthma with eosinophilic phenotype</td>
<td>30 mg administered subcutaneously, by a healthcare professional, every 4 weeks for the first three doses and then once every 8 weeks thereafter.</td>
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VI. Billing Code/Availability Information

**Jcode:**
- J3590 – Unclassified biologics
- C9466 – Injection, benralizumab, 1 mg (Hospital Outpatient Use ONLY)

**NDC:**
- 30 mg/mL single dose prefilled syringe: 00310-1730-xx
VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
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<tr>
<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.52</td>
<td>Severe persistent asthma with status asthmaticus</td>
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<tr>
<td>J82</td>
<td>Pulmonary eosinophilia, not elsewhere classified</td>
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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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<td>Noridian Healthcare Solutions, LLC</td>
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<td>6</td>
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<td>Novitas Solutions, Inc.</td>
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<td>First Coast Service Options, Inc.</td>
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