I. Length of Authorization

Coverage is provided for 6 months may be renewed.

II. Dosing Limits

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

Coverage is provided in the following conditions:

- Patient is at least 12 years of age; **AND**

**Universal Criteria**

- 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 \( \geq 150 \) cells/\( \mu L \) 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); ¶ 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**
  o 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**
  o Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Asthma with eosinophilic phenotype</td>
<td>Administer 30 mg subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter.</td>
</tr>
</tbody>
</table>

**NOTE:**
- Fasenra single-dose pre-filled syringe is for administration by a healthcare provider.
- 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.

VI. Billing Code/Availability Information

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

NDC:
- 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


### Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
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</table>
### 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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: [http://www.cms.gov/medicare-coverage-database/search.aspx](http://www.cms.gov/medicare-coverage-database/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/LCA): N/A

<table>
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<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>J82.81</td>
<td>Eosinophilic pneumonia, NOS</td>
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<tr>
<td>J82.82</td>
<td>Acute eosinophilic pneumonia</td>
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<tr>
<td>J82.83</td>
<td>Eosinophilic asthma</td>
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<tr>
<td>J82.89</td>
<td>Other pulmonary eosinophilia, not elsewhere classified</td>
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</table>

<table>
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<td>Noridian Healthcare Solutions, LLC</td>
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