Fasenra™ (benralizumab)

Last Review Date: September 25, 2019   Number: MG.MM.PH.44

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Definitions

Fasenra (benralizumab) is a humanized monoclonal antibody that directly binds to human interleukin-5 receptor. The IL-5 receptor is expressed on the surface of eosinophils and basophils which are involved in inflammation, an important component in the pathogenesis of asthma. By binding to the IL-5Rα chain, benralizumab reduces eosinophils through antibody-dependent cell-mediated cytotoxicity.

Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Dosage and Administration: Fasenra package insert

Guideline

Fasenra (benralizumab) may be considered medically necessary when the following criteria are met:

- Patient must be at least 12 years of age; AND
- Patient must have severe asthma, defined as one or more of the following:
  - 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; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within 6 weeks of dosing; **AND**
- Patient is not on concurrent treatment with another Interleukin-5 (IL-5) inhibitor (i.e. mepolizumab, reslizumab, etc); **AND**
- Must be used for add-on maintenance treatment in patients regularly receiving **BOTH** of the following:
  - High-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, etc.); **AND**
- Patient must have **ONE** of the following:
  - Two or more exacerbations in the previous year; **OR**
  - Require daily oral corticosteroids (for at least 3 days in addition to the regular maintenance therapy defined above)

Coverage for Fasenra (benralizumab) may be renewed when the following criteria are met:
- Treatment has resulted in clinical benefit, defined as one or more of the following:
  - Decreased use of systemic corticosteroids; **OR**
  - Decreased use of inhaled corticosteroid use for at least 3 days; **OR**
  - Decrease in hospitalizations; **OR**
  - Decrease in ER visits; **OR**
  - Decrease in unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

**Limitations and Exclusions**
- Initial and renewal approval will be granted for 6 months

**Revisions**

12/03/2018 Added J0517 and removed J3590, C9466 from Applicable Procedure Codes

**Applicable Procedure Codes**

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0517</td>
<td>Injection, benralizumab, 1 mg</td>
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**Applicable NDC’s**

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<th>Code</th>
<th>Description</th>
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<tr>
<td>0310-173-30</td>
<td>Fasenra 30mg single-dose prefilled syringe for injection</td>
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**Applicable Diagnosis Codes**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<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>
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References


