



## Fasenra™ (benralizumab)

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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-5R $\alpha$  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 FEV<sub>1</sub>) < 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  $\geq 150$  cells/ $\mu$ L 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 Fasentra (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 (FEV<sub>1</sub>)

#### Limitations and Exclusions

- Initial and renewal approval will be granted for 6 months

#### Revisions

12/3/2018 – Added J0517 and removed J3590, C9466 from Applicable Procedure Codes.

#### Applicable Procedure Codes

J0517	Injection, benralizumab, 1 mg
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#### Applicable NDC's

0310-173-30	Fasenra 30mg single-dose prefilled syringe for injection
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#### Applicable Diagnosis Codes

J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation

#### References

1. Fasentra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; November 2017. Accessed January 2018.

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. 2017 Update. Available from: <http://www.ginasthma.org>. Accessed November 2017.
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](http://www.ginasthma.org).