

Fasenra® (benralizumab)

When requesting Fasenra® (benralizumab), the individual requiring treatment must be diagnosed with the FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved indication(s)

Fasenra® (benralizumab) is indicated for add-on maintenance treatment of individuals with severe asthma having an eosinophilic phenotype

Approved Off-label Compendial use(s)

None

Coverage Guidelines

Severe Asthma with an eosinophilic phenotype

The individual must meet **all** of the following criteria for approval:

- Pretreatment blood eosinophil count greater than or equal to 300 cells/mcL
- Requires treatment to prevent asthma from becoming uncontrolled or remaining uncontrolled despite therapy with:
 - Inhaled or oral corticosteroids
 - Other controller medications, such as long-acting beta²-agonist (LABA) or leukotriene modifier/theophylline
- 12 years of age or older
- For reauthorization:
 - The individual must meet the following criteria for renewal:
 - Improvement of asthma control on Fasenra® as demonstrated by reduction in exacerbations and/or decrease in rescue medications

Approval duration (initial and reauthorization): 12 months

Dosing Recommendation

Recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter

References

1. Fasenra® prescribing information. Wilmington, DE: AstraZeneca Pharmaceuticals, LP: Issued November 2017.
2. Klasco RK (Ed): DRUGDEX® system. Thomson Micromedex, Greenwood Village, CO. Accessed January 8, 2018. <https://www.micromedexsolutions.com>
3. FitzGerald, J Mark et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomised, double-blinded, placebo-controlled phase 3 trial. *The Lancet*. 2017; 388(10056): 2128-2141. Accessed January 15, 2018. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31322-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31322-8/fulltext).
4. Bleecker, Eugene R et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β_2 -agonists (SIROCCO): a randomised, multicentre, placebo-controlled phase 3 trial. *The Lancet*. 2017; 388 (10056): 2115-2127. Accessed January 15, 2018. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31324-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31324-1/fulltext).
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014; 43:343-73. Accessed January 8, 2018. <https://www.ncbi.nlm.nih.gov/pubmed/24337046>
6. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention, Update 2017. Accessed January 8, 2018. <http://ginasthma.org/2017-gina-report-global-strategy-for-asthma-management-and-prevention/>.