

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Fasenra (benralizumab)
BENEFIT TYPE	Medical, Pharmacy
STATUS	Prior Authorization Required

Fasenra is an interleukin-5 (IL-5) receptor alpha-directed cytolytic monoclonal antibody. It was approved by the FDA in 2017 for the add-on maintenance treatment of severe asthma with an eosinophilic phenotype.

Fasenra (benralizumab) will be considered for coverage when the following criteria are met:

Severe Asthma

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist; AND
3. Member has a blood eosinophil count of at least 150 cells/ μ L; AND
4. Member has at least two documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least one requiring hospitalization, within the last 12 months; AND
5. Member's asthma has been uncontrolled after at least 3 months of conventional treatment with medium to high doses of inhaled corticosteroids (ICS) plus long-acting beta 2-agonists (LABA); AND
6. Medication is being used as add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
7. Medication is not used in conjunction with any other biologic therapy for asthma.
8. **Dosage allowed/Quantity limit:** 30 mg (1 syringe or pen) subQ every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Medication is not being used as monotherapy for asthma; AND
2. Chart notes have been provided showing improvement of signs and symptoms such as decreased frequency of emergency department visits or hospitalizations due to asthma exacerbations, increase in percent predicted FEV1 from pretreatment baseline, improved functional ability (e.g., exercise tolerance), and/or decreased utilization of rescue medications or oral corticosteroids.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Fasenra (benralizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/01/2017	New policy for Fasenra created.
05/12/2018	Baseline (pre-benralizumab treatment) peripheral blood eosinophil level was changed from 300 to ≥ 150 cells/ μ L within the past 6 weeks.
11/25/2020	Eosinophil count was updated to be consistent with guidelines; exacerbation number was updated to be consistent with guidelines (2 requiring OCS or 1 requiring hospitalization in the last year); changed from not to be used with Nucala or Cinqair to not to be used with any other asthma biologic.
02/23/2022	Transferred to new template. Annual review; no changes
11/20/2023	Changed eosinophil cutoff to 150. Added Pharmacy as benefit option. Rephrased renewal criteria. Updated references.

References:

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; 2021.
2. FitzGerald JM, Bleecker ER, Nair P, 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-blind, placebo-controlled phase 3 trial. *Lancet*. 2016;388(10056):2128-2141. doi:10.1016/S0140-6736(16)31322-8
3. Nair P, Wenzel S, Rabe KF, et al. Oral Glucocorticoid-Sparing Effect of Benralizumab in Severe Asthma. *N Engl J Med*. 2017;376(25):2448-2458. doi:10.1056/NEJMoa1703501
4. Bleecker ER, FitzGerald JM, Chanez P, 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. *Lancet*. 2016;388(10056):2115-2127. doi:10.1016/S0140-6736(16)31324-1
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.
6. Kostikas K, Brindicci C, Patalano F. Blood Eosinophils as Biomarkers to Drive Treatment Choices in Asthma and COPD. *Curr Drug Targets*. 2018;19(16):1882-1896. doi:10.2174/1389450119666180212120012
7. Farne HA, Wilson A, Milan S, Banchoff E, Yang F, Powell CV. Anti-IL-5 therapies for asthma. *Cochrane Database Syst Rev*. 2022;7(7):CD010834. Published 2022 Jul 12. doi:10.1002/14651858.CD010834.pub4
8. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. *Eur Respir J*. 2020;55(1):1900588. Published 2020 Jan 2. doi:10.1183/13993003.00588-2019
9. Global Initiative for Asthma (GINA). Difficult-To-Treat & Severe Asthma in Adolescent and Adult Patients, 2023. Available from www.ginasthma.org
10. Institute for Clinical and Economic Review (ICER). Biologic Therapies for Treatment of Asthma Associated with Type 2 Inflammation: Effectiveness, Value, and Value-Based Price Benchmarks. Final Evidence Report: December 20, 2018.

Effective date: 04/01/2024

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