CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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 6 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/µL; 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:**
   Age 12 years and older: 30 mg (1 syringe or pen) subQ every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.
   Age 6-11 years: based on body weight as below-

Body weight	Recommended Dosage
Less than 35 kg	10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
35 kg or more	30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then 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/μL 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.
04/18/2024	Lowered age limit from 12 years to 6 years and added dosing per drug label update.

References:

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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
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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: 10/01/2024
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