CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

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

Fasenra, approved by the FDA in 2017, is an interleukin-5 (IL-5) receptor alpha-directed cytolytic monoclonal antibody indicated for the add-on maintenance treatment of severe asthma with an eosinophilic phenotype, and for eosinophilic granulomatosis with polyangiitis (EGPA).
EGPA is a systemic necrotizing vasculitis that affects small-to-medium-sized vessels, belonging to the spectrum of antineutrophil cytoplasm antibody (ANCA)-associated vasculitides (AAV). Asthma is almost always present with EGPA. Cardiac involvement is the leading cause of death. Steroids are standard therapy. In the head-to-head MANDARA trial, Fasenra was non-inferior to Nucala for EGPA remission.

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.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist, immunologist, allergist, or rheumatologist; AND
3. Member has a confirmed diagnosis of EGPA with history or presence of both of the following:
   a) Asthma, and
   b) Documented eosinophilia (>1000 cells/µL and/or >10% of leucocytes); AND
4. Member has at least 2 of the following:
   a) Biopsy with eosinophilic vasculitis or perivascular/granulomatous inflammation
   b) Neuropathy
   c) Non-fixed pulmonary infiltrates
   d) Sino-nasal abnormality
   e) Cardiomyopathy
   f) Glomerulonephritis
   g) Alveolar hemorrhage
   h) Palpable purpura
   i) ANCA positivity (MPO or PR3); AND
5. Member has trialed and failed glucocorticoids with or without an immunosuppressant (e.g., azathioprine, methotrexate, mycophenolate mofetil); AND
6. Member meets one of the following:
   a) History of at least one relapse in the past 2 years, or
   b) Refractory disease: Failure to attain remission following at least 3 months of standard therapy; AND
7. Member does NOT have either of the following:
   a) Diagnosis of GPA or MPA
   b) Organ-threatening or imminently life-threatening EGPA.
8. **Dosage allowed/Quantity limit:** 30 mg subcutaneously every 4 weeks.
   QL: 1 pen or syringe per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes have been provided that show the member has demonstrated improvement (i.e., reduction in relapse rate, oral corticosteroid (OCS) dose, or blood eosinophil count).

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.
11/04/2024	New indication added for EGPA.

References:

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