

## Fasenra (benralizumab)

### Severe Asthma

#### Coverage Criteria:

1. Prescribed by an asthma specialist, allergist or pulmonologist; and,
2. Patient is  $\geq 6$  years of age and has a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the previous 6 weeks); and,
3. Patient has inadequate asthma control (see criteria #4) despite the following standard therapies:
  - a. Regular use of inhaled steroids (such as Flovent); and,
  - b. Regular use of a long-acting beta-agonist (such as Serevent); and,
  - c. Regular or periodic use of oral steroids; and,
4. Inadequate asthma control despite standard therapies is defined as one of the following:
  - a. At least 2 exacerbations requiring oral systemic corticosteroids in the last 12 months; or,
  - b. At least 1 exacerbation treated in a hospital or requiring mechanical ventilation in the last 12 months; and,
5. Patient is not currently using another biologic therapy for the treatment of asthma such as Cinqair, Dupixent, Nucala or Xolair; and,
6. Patient has tried and failed treatment with Nucala or Dupixent; and,
7. Prescribed within the FDA approved dosing regimen.

#### Renewal Criteria:

1. Patient has been seen by provider in the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient has not experienced unacceptable toxicity; and,
4. Patient has a clinically meaningful response to the medication as defined:
  - a. Decreased frequency of exacerbations defined as:
    - i. Improvement of asthma control, demonstrated by decreased use of oral or systemic corticosteroids; or,
    - ii. Less frequent hospitalizations; or,
    - iii. Reduced frequency of emergency department visits; or,
  - b. Improvement in lung function measured in FEV1; and,
5. Patient is not currently using another biologic therapy for the treatment of asthma such as Cinqair, Dupixent, Fasentra or Xolair; and,
6. Patient has tried and failed treatment with Nucala or Dupixent (members currently treated with Fasentra will be provided 60 days to transition); and,
7. Prescribed within FDA approved dosing regimen.

**Coverage Duration:**

Initial authorizations and reauthorizations will be provided for 12 months.

**Eosinophilic Granulomatosis with Polyangiitis****Coverage Criteria:**

1. Prescribed by an asthma specialist, allergist, pulmonologist or rheumatologist; and,
2. Patient is  $\geq 18$  years of age; and,
3. Patient is diagnosed with eosinophilic granulomatosis with polyangiitis (EGPA) with a history or presence of asthma with eosinophilia ( $>10\%$  eosinophils on the differential white blood cell count) and at least two of the following additional features of EGPA:
  - a. A biopsy showing histopathological evidence of eosinophilic vasculitis defined as:
    - i. Perivascular eosinophilic infiltration, or eosinophil-rich granulomatous; or,
    - ii. Inflammation; or,
  - b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality); or,
  - c. Pulmonary infiltrates, non-fixed; or,
  - d. Sino-nasal abnormality; or,
  - e. Cardiomyopathy (established by echocardiography or MRI); or,
  - f. Glomerulonephritis (hematuria, red cell casts or proteinuria); or,
  - g. Alveolar hemorrhage (by bronchoalveolar lavage); or,
  - h. Palpable purpura; or,
  - i. Positive test for ANCA (MPO or PR3); and,
4. Patient has tried and failed azathioprine or cyclophosphamide or methotrexate.  
Treatment failure is defined as one of the following:
  - a. EGPA flare requiring oral corticosteroid (OCS) dose increase or hospitalization; or,
  - b. EGPA symptom recurrence while tapering OCS dose; or,
  - c. Patient has contraindications or it is clinically inappropriate to use all immunosuppressant options listed above; and
5. Patient is not currently using another biologic therapy for the treatment of EGPA (e.g., Nucala); and,
6. Prescribed within FDA approved dosing regimen.

**Renewal Criteria:**

1. Patient has been seen by provider within the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient has a clinically meaningful response to the medication as defined:
  - a. Prednisolone or prednisone dose less than or equal to 4 mg/day; or
  - b. Remission: Prednisolone dose  $\leq 7.5$  mg/day (or equivalent OCS) and BVAS = 0 4.
4. Prescribed within the FDA-approved dosing regimen.

**Coverage Duration:**



Initial authorizations will be provided for 6 months.  
Reauthorizations will be provided for 12 months.