Fasenra (benralizumab)

INITIAL APPROVAL STANDARD REVIEW for up to 6 months**:**

The use of benralizumab meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes when **ALL** the following criteria are met:

ASTHMA

1. Individual is 6 years of age or older; **AND**
2. Individual has a diagnosis of severe eosinophilic asthma; **AND**
3. *Evidence of asthma as demonstrated by both of the following (GINA, 2022):
    a. A pretreatment forced expiratory volume in 1 second (FEV1) < 80% predicted for adults or ≤ 90% for children (< 18 years of age); **AND**
    b. Positive bronchodilator responsiveness test evidenced by an increase in FEV1 of > 12% and > 200 mL for adults and >12% for children (< 18 years of age). **AND**
4. Documentation of inadequate control of symptoms with use of one of the following combination therapies (ERS/ATS, 2014), unless the individual is intolerant of, or has a medical contraindication to these agents:
    a. 3 months of high-dose inhaled corticosteroid (ICS) (equivalent to those defined in the policy guidelines) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], or leukotriene receptor antagonist [LTRA], or theophylline); **OR**
    b. 6 months of ICS with daily oral glucocorticoids; **AND**
5. Individual has a blood eosinophil count of ≥ 150 cells/microliter at baseline prior to other eosinophil lowering therapy (e.g., systemic corticosteroids) and (without evidence of other potential causes of eosinophilia, such as hypereosinophilic syndromes, neoplastic disease, or parasitic infection) (Holguin, ATS, 2019); **AND**
6. Individual has one of the following (ERS/ATS, 2014):
    a. A history of 2 or more exacerbations in the previous year, requiring bursts of systemic steroids (>3 days each); **OR**
    b. At least one exacerbation requiring hospitalization, ICU stay or mechanical ventilation in the previous year; **AND**
7. Individual will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, LABA, LTRA or theophylline) in combination with benralizumab; **AND**
8. Individual is not being treated concurrently with another biologic agents for the same or similar condition (such as dupilumab, mepolizumab, omalizumab, reslizumab or tezepelumab); **AND**
9. Must be dosed in accordance with the FDA label; **AND**
10. Must be prescribed by or in consultation with an Allergist/Immunologist or Pulmonologist.

***FeNO testing is non-covered and is not considered adequate for establishing the diagnosis of asthma. Please see AR policy 2005020**

EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

INITIAL APPROVAL STANDARD REVIEW for up to 6 months:

1. Individual is 18 years of age or older; **AND**
2. Individual is diagnosed with relapsing or refractory eosinophilic granulomatosis with polyangiitis for 6 months or greater, defined as:
    a. A history or presence of asthma; **AND**
    b. Individual has a history or presence of a blood eosinophil count of more than 1,000 cells per microliter or a blood eosinophil level of greater than 10%; **AND**
    c. Individual has at least **two** of the following disease characteristics of EGPA:
        a. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation.
        b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
        c. Pulmonary infiltrates, non-fixed
        d. Sino-nasal abnormality
        e. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
        f. Glomerulonephritis (hematuria, red cell casts, proteinuria)
        g. Alveolar hemorrhage (by bronchoalveolar lavage)
        h. Palpable purpura
        i. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3); **AND**
3. Individual is currently taking oral corticosteroids and has been maintained on therapy for a minimum of 4 weeks, unless contraindicated or not tolerated; **AND**
4. Individual has had at least one relapse (i.e., requiring increase in oral corticosteroid dose, initiation/increased dose of immunosuppressive therapy or hospitalization within 2 years prior to starting treatment with the requested medication or has a refractory disease.

CONTINUED APPROVAL for up to 1 year:

ASTHMA

1. Treatment with benralizumab has resulted in clinical improvement as documented by one or more of the following:
    a. Decreased utilization of rescue medications, **OR**
    b. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids), hospitalizations, and/or ER/urgent visits, **OR**
    c. Increase in predicted FEV1 from pretreatment baseline; **AND**
2. Must be dosed in accordance with the FDA label.

EOSINOPHILIC GRANULOMATOSIS WITH POLYANGIITIS (EGPA)

1. Treatment with benralizumab has resulted in clinical improvement as documented by one or more of the following:
    a. A reduction in the frequency of relapses
    b. A reduction or discontinuation of daily oral corticosteroid dose
    c. No active vasculitis; AND
2. Must be dosed in accordance with the FDA label.

Dosage and Administration
Dosing per FDA Guidelines

Benralizumab is administered as a subcutaneous injection.

Please refer to the FDA label for dosing.

Please refer to a separate policy on Site of Care or Site of Service Review (policy #2018030) for pharmacologic/biologic medications.

Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Benralizumab, for any indication or circumstance not described above, including but not limited to the below listed indications, does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

1. Aspirin-exacerbated respiratory disease (AERD) or NSIAD-exacerbated respiratory disease (NERD) – consists of 3 clinical features: asthma, nasal polyps, and sensitivity to aspirin and other NSAIDs (No FDA labeled approval, 2021)
2. Atopic dermatitis
3. Eosinophilic esophagitis
4. Nasal polyposis
5. Hypereosinophilic syndromes (other than severe eosinophilic asthma)

For members with contracts without primary coverage criteria, benralizumab, for any indication or circumstance not described above, including but not limited to the below listed indications, is considered **investigational**. **Investigational** services are specific contract exclusions in most member benefit certificates of coverage.

1. Aspirin-exacerbated respiratory disease (AERD) or NSIAD-exacerbated respiratory disease (NERD) – consists of 3 clinical features: asthma, nasal polyps, and sensitivity to aspirin and other NSAIDs (No FDA labeled approval, 2021)
2. Atopic dermatitis
3. Eosinophilic esophagitis

4. Nasal polyposis
5. Hypereosinophilic syndromes (other than severe eosinophilic asthma)

Policy Guidelines

The ERS/ATS definition of high doses of various inhaled glucocorticoids in relation to patient age (in mcg/day):

Age 6 to 12 years

Beclomethasone ≥ 320 (HFA MDI)
Budesonide ≥ 800 (MDI or DPI); (≥ 720 mcg/day of US labeled budesonide DPI)
Ciclesonide ≥ 160 (HFA MDI)
Fluticasone propionate ≥ 500 (HFA MDI or DPI); (≥ 440 mcg/day of US labeled fluticasone HFA MDI)
Mometasone ≥ 500 (DPI); (≥ 550 mcg/day of US labeled mometasone DPI)

Age >12 years

Beclomethasone ≥ 1000 (HFA MDI)
Budesonide ≥ 1600 (MDI or DPI) ;(≥ 1440 mcg/day of US labeled budesonide DPI)
Ciclesonide ≥ 320 (HFA MDI)
Fluticasone propionate ≥ 1000 (HFA MDI or DPI); (≥ 880 mcg/day of US labeled fluticasone HFA MDI)
Mometasone ≥ 800 (DPI); (≥ 880 mcg/day of US labeled mometasone DPI

Note: Designation of high doses is provided from manufacturers' recommendations where possible. Equivalent high doses may be expressed differently between countries and some products (e.g., beclomethasone) are available in multiple formulations with different dosing recommendations. Medication inserts should be carefully reviewed by the clinician for the equivalent high daily dosage.