AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Fasenra			Page:	1 of 5
Effective Date:	11/6/2024			Last Review Date:	10/16/2024
Applies to:	☐New Jersey ☒ Pennsylvania Kids	☒Maryland ☐Virginia		☒Florida Kids ☒Kentucky PRMD	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Fasenra under the patient's prescription drug benefit.

Description:

FDA Approved Indication - Fasenra is indicated for:

A. Add-on maintenance treatment of adult and pediatric patients aged 6 years and older with severe asthma, and with an eosinophilic phenotype
   Limitations of Use:
   Not indicated for the relief of acute bronchospasm or status asthmaticus

B. Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

All other indications are considered experimental/investigational and not medically necessary.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

Applicable Drug List:

Fasenra

Policy/Guideline:

Documentation:

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial requests for Asthma:
   a) Chart notes or medical record documentation showing pretreatment blood eosinophil count, dependance on systemic corticosteroids if applicable.
   b) Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
   c) The member is unable to take Dupixent for the given diagnosis due to a trial and inadequate treatment response or intolerance, or a contraindication. Documentation is required for approval.
2. Continuation requests for Asthma:
   a) Chart notes or medical record documentation supporting improvement in asthma control.
3. Initial requests for EGPA:
   a) Chart notes or medical record documentation showing pretreatment blood eosinophil count.

b) Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration. If therapy is not advisable, documentation of clinical reason to avoid therapy.

4. Continuation requests for EGPA:
   a) Chart notes or medical record documentation supporting improvement in EGPA control.

Prescriber Specialties

For the indication of asthma: This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Asthma Criteria for Initial Approval:

Authorization may be granted for members 6 years of age or older when ALL the following criteria are met:

1. Patient has previously received a biologic drug indicated for asthma in the past year.
   a) Note: Requests will require that the patient is unable to take Dupixent due to a trial and inadequate treatment response or intolerance, or a contraindication.
2. Member will NOT use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

OR

Authorization may be granted for treatment of asthma when ALL the following criteria are met:

1. Member is 6 years of age or older.
2. Medication must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist
3. Member meets EITHER of the following criteria:
   a. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
   b. Member is dependent on systemic corticosteroids
4. Member has uncontrolled asthma as demonstrated by experiencing at least ONE of the following within the past year:
   a. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
   b. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.

c. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).

5. Member has inadequate asthma control despite current treatment with BOTH of the following medications at optimized doses:
    a. High dose inhaled corticosteroid
    b. Additional controller (i.e., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
6. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Fasenra.
7. Member will NOT use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

<u>Eosinophilic Granulomatosis with Polyangiitis (EGPA) for Initial Approval:</u>
Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a history or the presence of a blood eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%.
3. Member is currently taking oral corticosteroids, unless contraindicated or not tolerated.
4. Member has at least two of the following disease characteristics of EGPA:
    i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
    ii. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality)
    iii. Pulmonary infiltrates, non-fixed
    iv. Sino-nasal abnormality
    v. Cardiomyopathy (established by echocardiography or magnetic resonance imaging)
    vi. Glomerulonephritis (hematuria, red cell casts, proteinuria)
    vii. Alveolar hemorrhage (by bronchoalveolar lavage)
    viii. Palpable purpura
    ix. Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)
5. Member 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.

Asthma Criteria for Continuation of Therapy:

Authorization may be granted for treatment of asthma when ALL the following criteria are met:

1. Member is 6 years of age or older
2. Asthma control has improved on Fasenra treatment as demonstrated by at least ONE of the following:
   a. A reduction in the frequency and/or severity of symptoms and exacerbations
   b. A reduction in the daily maintenance oral corticosteroid dose
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Fasenra.
4. Member will NOT use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Eosinophilic Granulomatosis with Polyangiitis (EGPA) for Continuation of Therapy:

Authorization of 12 months may be granted for continuation of treatment of EGPA when all of the following criteria are met:

1. Member is 18 years of age or older.
2. Member has a beneficial response to treatment with the requested medication as demonstrated by any 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

Approval Duration and Quantity Restrictions:

Initial Approval for Asthma: 6 months
Initial Approval for EGPA: 12 months
Renewal Approval: 12 months

Quantity Level Limit:

Medication	Standard Limit	FDA-recommended dosing
Fasenra (benralizumab) 30 mg/mL single-dose prefilled syringe/autoinjector	1 syringe/autoinjector per 30 days	**Asthma** Adults and adolescent patients 12 years of age and older: 30 mg every 4 weeks for the first 3 doses, followed by 30 mg every 8 weeks Pediatric patients 6 to 11 years of age: • < 35 kg: 10 mg every 4 weeks for the first 3 doses, followed by 10 mg every 8 weeks • ≥ 35 kg: 30 mg every 4 weeks for the first 3 doses, followed by 30 mg every 8 weeks **Eosinophilic granulomatosis with polyangiitis (EGPA)** 30 mg every 4 weeks
Fasenra (benralizumab) 10 mg/0.5 mL single-dose prefilled syringe	1 syringe per 60 days	

References:

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; September 2024.
2. Nair P, Wenzel S, Rabe K, et al. Oral glucocorticoid-sparing effect of benralizumab in severe asthma. N Engl J Med. 2017;376:2448-2458.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 update. Available at: https://ginasthma.org/wp-content/uploads/2023/07/GINA-Full-Report-23_07_06-WMS.pdf. Accessed March 8, 2024.
4. American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 8, 2024.
5. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.
6. AstraZeneca. Efficacy and Safety of Benralizumab in EGPA Compared to Mepolizumab. (MANDARA) Available from https://clinicaltrials.gov/ct2/show/record/NCT04157348. NLM identifier: NCT04157348. Accessed September 20, 2024.
7. Groh M, Pagnoux C, Baldini C, et al. Eosinophilic granulomatosis with polyangiitis (Churg–Strauss) (EGPA) Consensus Task Force Recommendations for evaluation and management. Eur J Intern Med. 2015;26(7):545-553.
8. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Rheumatol. 2021;73(8):1366-1383.