Effective Date: 12/2018
Reviewed: 12/18, 7/19, 4/20, 3/21, 2/22, 1/23, 12/23, 4/24, 5/24, 1/25 Pharmacy Scope: Medicaid Medical Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

SPECIALTY GUIDELINE MANAGEMENT

FASENRA (benralizumab)

POLICY

Summary of Evidence:
Clinical trials evaluating the efficacy and safety of Fasenra in the treatment of severe eosinophilic asthma have demonstrated significant reductions in asthma exacerbations, improvements in lung function, and reductions in daily oral corticosteroid use compared to placebo. Clinical trials evaluating the efficacy of Fasenra in the treatment of eosinophilic granulomatosis with polyangiitis (EGPA) have demonstrated non-inferiority to mepolizumab in achieving remission, with a high proportion of patients achieving complete oral corticosteroid reduction and similar relapse rates. Fasenra is a monoclonal antibody that binds to the alpha subunit of the interleukin-5 receptor, leading to rapid and near-complete depletion of eosinophils, which are associated with asthma exacerbations and airway inflammation. The most common adverse reactions are headache, pharyngitis, and injection site reactions.

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications:

1. Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
2. Fasenra is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Limitations of Use:

- Not for treatment of other eosinophilic conditions
- Not for relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Universal Criteria:

A. Member will not use Fasenra concomitantly with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenra, Nucala, Xolair, Tezspire, etc)
B. Must NOT be used for either of the following:
    a. Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, hypereosinophilic syndrome, etc.)
    b. Relief of acute bronchospasm or status asthmaticus
C. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

Severe Asthma:

Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:

A. Member is 6 years of age or older.
B. Member has clinically documented severe asthma (see Appendix)
C. Member has asthma with an eosinophilic phenotype with documentation of blood eosinophil count of ≥150 cells per μL within 6 weeks of starting therapy OR member is dependent on systemic corticosteroids.
D. Used for add-on maintenance treatment in members regularly receiving BOTH of the following**:**
    1. Medium to high-dose inhaled corticosteroids
    2. An additional controller medication (e.g., long-acting beta agonist, long-acting muscarinic agent, leukotriene modifiers, etc.)
E. Documentation that the member has inadequate asthma control with two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above)
F. Baseline measurements of at least one of the following for assessment of clinical status:
    1. Use of systemic corticosteroids
    2. Use of inhaled corticosteroids
    3. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    4. Forced expiratory volume in 1 second (FEV_1)

Eosinophilic Granulomatosis with Polyangiitis (EGPA):

Authorization of 6 months may be granted for treatment of EGPA when all of the following criteria are met:

A. Member is 18 years of age or older.
B. Documentation that the member has a confirmed diagnosis of EGPA (see Appendix).

C. Documentation that the member has relapsing or refractory disease
D. Member has received prior treatment with oral corticosteroids with or without immunosuppressive therapy
E. Member has been on a stable dose of oral corticosteroid therapy for at least 4 weeks prior to starting treatment.
F. Physician has documentation of assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses, etc.)

III. CONTINUATION OF THERAPY

A. Member continues to meet the universal and other indication-specific relevant criteria identified in section II; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: parasitic (helminth) infection, severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash), etc.; **AND**

Severe Asthma
Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:

A. Improvement in asthma symptoms or asthma exacerbations as evidenced by documentation of a decrease in one or more of the following:
   a. Use of systemic corticosteroids
   b. Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
   c. Hospitalizations
   d. ER visits
   e. Unscheduled visits to healthcare provider; **OR**
B. Improvement from baseline in forced expiratory volume in 1 second (FEV_1)

Eosinophilic Granulomatosis with Polyangiitis (EGPA):

Authorization of 12 months may be granted for treatment of EGPA when all of the following criteria are met:
Disease response as indicated by documentation of improvement in signs and symptoms compared to baseline as evidenced by one or more of the following:
   a. Member is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 (no active vasculitis) plus a prednisone/prednisolone daily dose of ≤ 7.5 mg]

b. Decreased frequency in the occurrence of relapses
c. Decrease in the daily oral corticosteroid dose
d. Improvement on a disease activity scoring tool [e.g., Vasculitis Damage Index (VDI), Birmingham Vasculitis Activity Score (BVAS), Forced vital capacity (FVC), Forced Expiratory Volume during first second (FEV1), Asthma Control Questionnaire (6-item version) (ACQ-6), etc.]

IV. QUANTITY LIMIT

Severe Asthma:

- Fasenra 10mg/0.5ml syringe has a quantity limit of 1 syringe per 56 days, with post-limit of 3 syringes per 84 days.
- Fasenra 30mg/ml has a quantity limit of 1 syringe per 56 days, with post-limit of 3 syringes per 84 days.

EGPA:

- A quantity limit exception of 1 syringe per 28 days (daily dose of 0.04) will be provided for members receiving Fasenra 30mg/ml for EGPA.

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale:
Fasenra was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Fasenra according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

V. DOSAGE/ADMINISTRATION:

Indication	Dose	Maximum dose (1 billable unit = *1* mg)
Severe Asthma with eosinophilic phenotype	**Adult and Adolescent Patients 12 Years of Age and Older:** • 30 mg administered subcutaneously, every 4 weeks for the first three doses and then once every 8 weeks thereafter **Pediatric patients 6 to 11 years of age:** • *Less than 35 kg:* 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter • *35kg or more:* 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter. NOTE: • Fasenra single-dose pre-filled syringe is for administration by a healthcare provider. • Fasenra Pen single-dose autoinjector is intended for administration by patients/caregivers. Patients/caregivers may inject after proper training in subcutaneous injection technique, and after the healthcare provider determines it is appropriate.	**Adult and Adolescent Patients 12 Years of Age and Older:** Loading: 30 mg (30 units) every 28 days x 3 doses Maintenance: 30 mg (30 units) every 56 days **Pediatric patients 6 to 11 years of age less than 35kg:** Loading: 10 mg (10 units) every 28 days x 3 doses Maintenance: 10 mg (10 units) every 56 days **Pediatric patients 6 to 11 years of age less than 35kg:** Loading: 30 mg (30 units) every 28 days x 3 doses Maintenance: 30 mg (30 units) every 56 days
Eosinophilic Granulomatosis	**Adult patients 18 years of age and older:**	**Adult patients 18 years of age and older:**

with Polyangiitis (EGPA)	• 30 mg administered subcutaneously, every 4 weeks.	• 30 mg (30units) administered subcutaneously, every 4 weeks.

VI. HCPCS code

HCPCS/CPT Code	Description
J0517	Injection, benralizumab, 1mg

VII. APPENDIX

Components of Severity for Classifying Asthma as Severe may include any of the following (not all-inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Eosinophilic Granulomatosis Polyangiitis (EGPA) defined as all of the following:

1. History of presence of asthma
2. Blood eosinophil level > 10% or an absolute eosinophil count >1000 cells/mm^3
3. Two or more of the following criteria:
   a. Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation
   b. Neuropathy
   c. Pulmonary infiltrates
   d. Sinonasal abnormalities
   e. Cardiomyopathy
   f. Glomerulonephritis
   g. Alveolar hemorrhage
   h. Palpable purpura
   i. Antineutrophil Cytoplasmic Antibody (ANCA) positivity

References:

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