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SPECIALTY GUIDELINE MANAGEMENT

FASENRA (benralizumab)

POLICY

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:

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

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;

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. Documentation that the 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. Documentation that the member is using Fasenra as add on maintenance treatment who are regularly receiving BOTH of the following:
    1. Medium to high-dose inhaled corticosteroid
    2. Additional controller medication (long acting $beta_2$-agonist, long-acting muscarinic antagonists, , leukotriene modifier, etc.), unless contraindicated or not tolerated.
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. Documentation of 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 member has relapsing or refractory disease
D. Documentation that the member has received prior treatment with oral corticosteroids with or without immunosuppressive therapy
E. Documentation that the member has been on a stable dose or oral corticosteroid therapy for at least 4 weeks prior to starting treatment
F. Documentation that Physician has assessed baseline 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:
   i. Use of systemic corticosteroids
   ii. Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
   iii. Hospitalizations
   iv. ER visits
   v. 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:

A. 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. Patient is in remission [defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 (no active vasculitis) and a prednisone/prednisolone daily dose of ≤ 7.5 mg]
   b. Decreased frequency in the occurrences of relapses
   c. Decrease in 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.]

I. QUANTITY LIMIT

Severe Asthma:

- Fasenra 10mg/0.5ml 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 0.04) will be provided for members receiving Fasenra 30mg/ml for EGPA.

II. 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 with Polyangiitis (EGPA)	**Adult patients 18 years of age and older:** • 30 mg administered subcutaneously, every 4 weeks.	**Adult patients 18 years of age and older:** • 30 mg (30 units) administered subcutaneously, every 4 weeks.

III. HCPCS code

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

IV. 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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