Fasenra (benralizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Fasenra (benralizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. The indications below including FDA-approved indications and compendial uses are considered covered benefits 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:

A. Add-on maintenance treatment of patients with severe asthma aged 6 years and older, and with an eosinophilic phenotype.
B. 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

POLICY

Documentation

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

A. Asthma
    1. For initial requests:
        a. Member’s chart or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.

b. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

2. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

B. Eosinophilic granulomatosis with polyangiitis (EGPA)
1. For initial requests:
   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
2. For continuation requests: Chart notes or medical record documentation supporting improvement in EGPA control.

Prescriber Specialties

This medication must be prescribed by or in consultation with an allergist/immunologist or pulmonologist.

Criteria for Initial Approval

A. Asthma

1. Authorization of **6 months** may be granted for members 6 years of age or older who have previously received a biologic drug (e.g., Fasenra Nucala, Tezspire, Xolair, Cinqair) indicated for asthma.

2. Authorization of **6 months** may be granted for treatment of severe asthma with an eosinophilic phenotype when ALL of the following criteria are met:
   A. Member is 6 years of age or older
   B. Member meets either of the following criteria:
      i. Member has a baseline blood eosinophil count of at least 150 cells per microliter; or
      ii. Member is dependent on systemic corticosteroids
   C. Member has uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
      i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment
      ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit
      iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
   D. Member has inadequate asthma control despite current treatment with both of the following medications at maximally tolerated doses:
      i. Medium-to-high dose inhaled corticosteroid
      ii. Additional controller (i.e., long-acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   E. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Fasenra
   F. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair)

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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 an 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:

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)

5. Member has had at least one relapse (i.e., requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Fasenra or has a refractory disease.

Continuation of Therapy

A. Asthma

Authorization of **12 months** may be granted for treatment of severe asthma with an eosinophilic phenotype when ALL of 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 Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair).

B. Eosinophilic granulomatosis with polyangiitis (EGPA)

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 Fasenra as demonstrated by any of the following:
   a. A reduction in the frequency of relapses, or
   b. A reduction or discontinuation of daily oral corticosteroid dose, or
   c. No active vasculitis

Other

For all indications: Member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

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.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Maintenance	Loading Dose	FDA-recommended dosing
Fasenra 30 mg/mL single-dose prefilled syringe/autoinjector	1 syringe/pen per 56 days	3 syringes per first 84 days	**Asthma** Initial: 30 mg every 4 weeks for the first 3 doses Maintenance: 30 mg every 8 weeks
	1 syringe/pen per 28 days	N/A	**Eosinophilic granulomatosis with polyangiitis (EGPA)** Maintenance: 30 mg every 4 weeks
Fasenra 10 mg/mL single-dose prefilled syringe	1 syringe per 56 days	3 syringes per first 84 days	**Asthma** Initial: 10 mg every 4 weeks for the first 3 doses Maintenance: 10 mg every 8 weeks

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J0517 Fasenra, Injection, benralizumab, 1mg

REFERENCES

- Fasenra [package insert]. Wilmington, DE: AstraZeneca; September 2024.
- 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
- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2019. http://ginasthma.org/gina-reports/. Accessed March 5, 2021.
- American Academy of Allergy, Asthma & Immunology (AAAAI) 2020 Virtual Annual Meeting. Available at: https://annualmeeting.aaaai.org/. Accessed March 5, 2021.
- 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.

POLICY HISTORY

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