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 the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

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. For initial requests:
    1. Member’s chart or medical record showing pretreatment blood eosinophil count, dependence on systemic corticosteroids if applicable.
    2. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.
B. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

Criteria for Initial Approval

Authorization of 6 months may be granted for treatment of severe asthma with an eosinophilic phenotype when all of the following criteria are met:

1. Member is 12 years of age or older
2. 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
3. Member has severe asthma as defined by inadequate asthma control (e.g., hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimized doses:
   a.) Inhaled corticosteroid
   b.) Additional controller (long-acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
4. Member will not use Fasenra as monotherapy
5. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair)

Continuation of Therapy

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 12 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 not use Fasenra as monotherapy
4. Member will not use Fasenra concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Nucala, Tezspire, Xolair)

Other

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.

Medication	Maintenance	Loading Dose	FDA-recommended dosing
Fasenra 30 mg/mL single-dose prefilled syringe/autoinjector	1 syringe per 56 days	3 syringes per first 84 days	Initial: 30 mg every 4 weeks for the first 3 doses Maintenance: 30 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; February 2021.
- 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.

POLICY HISTORY

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