

Effective Date: 12/2018
Reviewed: 12/18, 7/19, 4/20, 3/21, 2/22, 1/23, 12/23, 4/24, 5/24
Pharmacy Scope: Medicaid

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 Indication

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

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

II. DOCUMENTATION

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

A. Initial requests:

1. Documentation of baseline blood eosinophil count and components of severity that classify asthma as severe
2. Baseline documentation of one of the following:
 - a. Use of systemic corticosteroids
 - b. Use of inhaled corticosteroids
 - c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
 - d. Forced expiratory volume in 1 second (FEV1)

B. Continuation of therapy requests: documentation of improved asthma control

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III. CRITERIA FOR INITIAL APPROVAL

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

- A. Member is 12 years of age or older.
- B. Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
- C. Member has clinically documented severe asthma (see Appendix).
- D. 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.
- E. Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months:
 - 1. Inhaled corticosteroid
 - 2. Additional controller medication (long acting beta₂-agonist, long-acting muscarinic antagonists, , leukotriene modifier), unless contraindicated or not tolerated
- F. Must NOT be used for either of the following:
 - 1. Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
 - 2. Relief of acute bronchospasm or status asthmaticus;
- G. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations).
- H. 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 (FEV₁)
- I. 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)
- J. Member will use Fasenra as add-on maintenance treatment.

IV. CONTINUATION OF THERAPY

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

- A. Member is 12 years of age or older.
- B. Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
- C. Member is tolerating treatment.
- D. Improvement in asthma symptoms or asthma exacerbations as evidenced by 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
 - f. Improvement from baseline in forced expiratory volume in 1 second (FEV₁); AND
- E. Member will use Fasenera as add-on maintenance treatment.
- F. Member will not use Fasenera concomitantly with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenera, Nucala, Xolair, Tezspire)

II. QUANTITY LIMIT

Fasenera has a quantity limit of 1 syringe per 56 days, with post-limit of 3 syringes per 84 days.

III. DOSAGE/ADMINISTRATION:

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
Severe Asthma with eosinophilic phenotype	<p>Adult and Adolescent Patients 12 Years of Age and Older:</p> <ul style="list-style-type: none"> • 30 mg administered subcutaneously, every 4 weeks for the first three doses and then once every 8 weeks thereafter <p>Pediatric patients 6 to 11 years of age:</p> <ul style="list-style-type: none"> • 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. 	<p>Adult and Adolescent Patients 12 Years of Age and Older:</p> <p><u>Loading:</u> 30 mg (30 units) every 28 days x 3 doses</p> <p><u>Maintenance:</u> 30 mg (30 units) every 56 days</p> <p>Pediatric patients 6 to 11 years of age less than 35kg:</p> <p><u>Loading:</u> 10 mg (10 units) every 28 days x 3 doses</p> <p><u>Maintenance:</u> 10 mg (10 units) every 56 days</p> <p>Pediatric patients 6 to 11 years of age less than 35kg:</p> <p><u>Loading:</u> 30 mg (30 units) every 28 days x 3 doses</p> <p><u>Maintenance:</u> 30 mg (30 units) every 56 days</p>

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	<p>NOTE:</p> <ul style="list-style-type: none"> • 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. 	
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IV. HCPCS code

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

V. 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

References:

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; February 2024. Accessed April 2024.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report
3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007. 3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: <http://www.ginasthma.org>. Accessed August 2018.

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4. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. *J Asthma Allergy*. 2014; 7: 53–65.
5. Goldman M, Hirsch I, Zangrilli JG, et al. The association between blood eosinophil count and benralizumab efficacy for patients with severe, uncontrolled asthma: subanalyses of the Phase III SIROCCO and CALIMA studies. *Curr Med Res Opin*. 2017 Sep;33(9):1605- 1613. doi: 10.1080/03007995.2017.1347091. Epub 2017 Jul 19.
6. The Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2017. Available from: www.ginasthma.org.
7. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. *Eur Respir J* 2014; 43: 343-373.