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 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. 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.

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 6 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

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 6 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 beta$_2$-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 (FEV_1)
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.
K. MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

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 6 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 (FEV_1); AND
E. Member will use Fasenra as add-on maintenance treatment.
F. 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

II. QUANTITY LIMIT

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

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.

III. 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	**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

	after the healthcare provider determines it is appropriate.	

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 April2024.
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.
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.