CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Fasenra (benralizumab)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Office/Outpatient Hospital
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 30 mg/mL
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Fasenra (benralizumab) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

SEVERE ASTHMA

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by or under the recommendation of a pulmonologist, immunologist or allergist; AND
3. Member has eosinophilic phenotype as defined by a baseline (pre-benralizumab treatment) peripheral blood eosinophil level ≥ 150 cells/μL within the past 6 weeks; AND
4. Member's asthma has been inadequately controlled after 3 month of conventional treatment of medium to high doses of inhaled corticosteroids (ICS) and long acting beta 2-agonists (LABA); AND
5. Member has at least two documented severe asthma exacerbation within last year; AND
6. Medication is being used as the add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
7. Medication is not used in combination with Nucala (mepolizumab) or Cinqair (reslizumab).
8. **Dosage allowed:** Recommended dose is 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.

If member meets all the requirements listed above, the medication will be approved for 16 weeks.

For **reauthorization**:

1. Medication not being used as monotherapy for asthma; AND
2. Member must be in compliance with all other initial criteria; AND
3. Chart notes have been provided that show the member has demonstrated improvement during 16 weeks of medication therapy:
   a) Decreased frequency of emergency department visits; OR
   b) Decreased frequency of hospitalizations due to asthma symptoms; OR
   c) Increase in percent predicted FEV1 from pretreatment baseline; OR
   d) Improved functional ability (i.e. decreased effect of asthma on ability to exercise, function in school or at work, or quality of sleep); OR
   e) Decreased utilization of rescue medications.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Fasenra (benralizumab) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Active lung infection
- Acute bronchospasm
- Allergic bronchopulmonary aspergillosis/mycosis
- Alpha 1 anti-trypsin deficiency
- Atopic dermatitis
- Atopic eczema
- Bronchiectasis
- Chronic obstructive pulmonary disease
- Chronic rhinosinusitis
- Churg-Strauss syndrome
- Cystic fibrosis
- Eosinophil gastroenteritis
- Eosinophilic esophagitis
- Eosinophilic granulomatosis with polyangiitis
- Hyper-eosinophilic syndrome
- Hypoventilation syndrome associated with obesity
- Lung cancer
- Nasal polyposis
- Primary ciliary dyskinesia
- Pulmonary fibrosis
- Status asthmaticus

DATE	ACTION/DESCRIPTION
12/01/2017	New policy for Fasenra created.
05/12/2018	Baseline (pre-benralizumab treatment) peripheral blood eosinophil level was changed from 300 to ≥ 150 cells/μL within the past 6 weeks.

References:

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2017.
2. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT01914757 Efficacy and Safety Study of Benralizumab in Adults and Adolescents Inadequately Controlled on Inhaled Corticosteroid Plus Long-acting β2 Agonist. Available at: https://clinicaltrials.gov/ct2/show/NCT01914757?term=benralizumab&recrs=e&draw=1&rank=6.
3. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective. J Asthma Allergy. 2014;7:53–65.
4. ClinicalTrials.gov web site. U.S. National Library of Medicine. Identifier NCT02075255. Efficacy and Safety Study of Benralizumab to Reduce OCS Use in Patients With Uncontrolled Asthma on High Dose Inhaled Corticosteroid Plus LABA and Chronic OCS Therapy. Available at: https://clinicaltrials.gov/ct2/show/NCT02075255?term=benralizumab&recrs=e&draw=1&rank=7.
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.

Effective date: 09/07/2018
Revised date: 05/12/2018