CareSource Rxinnovations

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Fasenra (benralizumab)
BILLING CODE	J0517
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient Hospital
STATUS	Prior Authorization Required

Fasenra (benralizumab) is an IL-5 receptor blocker and monoclonal antibody. It was approved by the FDA in 2017 for the treatment of severe eosinophilic asthma.

Fasenra (benralizumab) will be considered for coverage when the following criteria are met:

Severe Asthma

For **initial** authorization:

1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist, immunologist, or pulmonologist; AND
3. Member has a blood eosinophil count of at least 300 cells/μL or at least 150 cells/ μL if taking maintenance oral corticosteroids (OCS); AND
4. Member has at least two documented severe asthma exacerbations requiring oral corticosteroids (OCS), or at least one requiring hospitalization, within last year; AND
5. 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
6. Medication is being used as add-on maintenance treatment to conventional therapies for asthma (i.e., ICS, LABA, etc.); AND
7. Medication is not used in conjunction with any other biologic therapy for asthma.
8. **Dosage allowed/Quantity limit:** 30 mg (1 syringe or pen) every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter.

If all the above requirements are met, the medication will be approved for 16 weeks.

For **reauthorization**:

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

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Fasenra (benralizumab) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
11/25/2020	Eosinophil count was updated to be consistent with guidelines; exacerbation number was updated to be consistent with guidelines (2 requiring OCS or 1 requiring hospitalization in the last year); changed from not to be used with Nucala or Cinqair to not to be used with any other asthma biologic.
02/23/2022	Transferred to new template. Annual review; no changes

References:

1. Fasenra [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals; October 2019.
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.
6. Difficult-To-Treat & Severe Asthma in Adolescent and Adult Patients: Diagnosis and Management. Global Initiative For Asthma (GINA); Apr. 2019. Available at: https://ginasthma.org/wp-content/uploads/2018/11/GINA-SA-FINAL-wms.pdf.
7. Kostikas K, Brindicci C, Patalano F. Blood Eosinophils as Biomarkers to Drive Treatment Choices in Asthma and COPD. Curr Drug Targets. 2018;19(16):1882-1896. doi:10.2174/1389450119666180212120012
8. 2020 Focused Updates To The Asthma Management Guidelines. National Institute of Health; Dec 2020. Available at: https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates.

Effective date: 01/01/2023
Revised date: 02/23/2022