Benralizumab (Fasenra®)

NDC CODE(S) 00310-1730-XX FASENRA 30MG/ML Solution Prefilled Syringe (ASTRAZENECA)
00310-1830-XX FASENRA PEN 30MG/ML Solution Auto-Injector (ASTRAZENECA)

DESCRIPTION

Benralizumab is a humanized alpha-directed cytolytic monoclonal antibody (IgG1, kappa) that directly binds to the alpha subunit of the human interleukin-5 receptor (IL-5Rα). The IL-5 receptor is expressed on the surface of eosinophils and basophils.

By binding to the IL-5Rα chain, benralizumab reduces eosinophils through antibody-dependent cell-mediated cytotoxicity (ADCC). A reduction in blood eosinophil counts was observed 24 hours post dosing; however the actual mechanism of benralizumab action in asthma has not been definitively established.

POLICY

- Benralizumab is considered ***medically necessary*** for the treatment of asthma if the medical appropriateness criteria are met: **(See Medical Appropriateness below.)**
- Benralizumab for the treatment of other conditions/diseases is considered ***investigational*** including but not limited to the following:
  - Treatment of other eosinophilic conditions
  - Relief of acute bronchospasm or status asthmaticus

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

Universal Criteria

- Must not be used in combination with another monoclonal antibody (e.g., omalizumab, mepolizumab, reslizumab, etc.); **AND**

Severe Asthma

- Patient is at least 12 years of age; **AND**
- Patient must have severe* disease; **AND**
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/μL within 6 weeks of dosing; **AND**
- Must be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
  - Medium to high-dose inhaled corticosteroids; **AND**
  - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers, etc.); **AND**
- Must NOT be used for either of the following:
  - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
  - Relief of acute bronchospasm or status asthmaticus; **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**

- Baseline measurement of at least one of the following for assessment of clinical status:
  - Use of systemic corticosteroids
  - Use of inhaled corticosteroids
  - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
  - Forced expiratory volume in 1 second (FEV1)

*Components of severity for classifying asthma as severe may include any of the following (not all inclusive):
• Symptoms throughout the day
• Nighttime awakenings often 7x/week
• SABA use for symptom control occurs several times per day
• Extremely limited normal activities
• Lung function (percent predicted FEV1) < 60%
• Exacerbations requiring oral systemic corticosteroids are generally more frequent & intense relative to moderate asthma

RENEWAL CRITERIA

- Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Approval Criteria; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: parasitic (helminth) infection, severe hypersensitivity reactions, etc.; **AND**
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider; **OR**
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Severe Asthma with eosinophilic phenotype	30 mg administered subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter.

LENGTH OF AUTHORIZATION

Coverage is provided for six months and is eligible for renewal.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

Severe Asthma with an eosinophilic phenotype

- Load: 30 billable units every 28 days for 3 doses
- Maintenance: 30 billable units every 56 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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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.
8. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55: 1900588 [https://doi.org/10.1183/13993003.00588-2019].
9. Lexi-Comp Online. (2020). AHFS DI. Benralizumab. Retrieved October 12, 2020 from Lexi-Comp Online with AHFS.
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BlueCross BlueShield of Tennessee

Policy

Medical Policy Manual **Approved Revision: Do Not Implement Until 6/30/21**

EFFECTIVE DATE 6/30/2021

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