Medical Policy

Farsenra® (benralizumab)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-052
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Fasenra® (benralizumab) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Initial coverage for Fasenra will be provided for 6 months and may be renewed. Continued coverage will be provided for 12 months.

Initial Therapy

1. Patient has a diagnosis of severe asthma; **AND**
2. Patient is 12 years of age and older; **AND**
3. Fasenra is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**

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4. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting one of the following:

    a. Asthma is an eosinophilic phenotype as defined by patient having a blood eosinophil count of ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy; **AND**

    Note: Examples of anti-interleukin-5 therapies include Fasenra, Nucala, Cinqair, etc.
5. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following:
    a. An inhaled corticosteroid; **AND**
    b. At least one additional asthma controller/maintenance medication; **AND**
    Note:
        - An exception to the requirement for a trial of one additional asthma controller/maintenance medication (criterion b) can be made if the patient has already received anti-interleukin-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an inhaled corticosteroid for **at least 3 consecutive months.**
        - Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta2-agonist would fulfil the requirement for both criteria a and b.
        Examples of inhaled corticosteroids include Aerospan, Alvesco, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twisthaler/HFA, Flovent Diskus/HFA, Pulmicort Flexhaler, Qvar/Qvar RediHaler, and budesonide suspension for inhalation (Pulmicort Respules, generics).
        Examples of additional asthma controller/maintenance medications include long-acting beta2-agonists (e.g., Serevent Diskus); inhaled long-acting muscarinic antagonists (e.g., Spiriva Respimat); leukotriene receptor antagonists (e.g., montelukast tablets/granules [Singulair, generics], zafirlukast tablets [Accolate, generics]); theophylline (e.g., Theo 24, TheoChron ER, generics).
        Examples of combination inhaled corticosteroid/long-acting beta2-agonist inhalers include Advair Diskus (generic Wixela Inhub; authorized generics), Advair HFA, AirDuo RespiClick (authorized generics), Breo Ellipta, Dulera, Symbicort.
6. Patient's asthma is uncontrolled or inadequately controlled prior to starting any anti-interleukin therapy as defined by **ONE** of the following:
    a. The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
    b. The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year; **OR**
    c. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
    d. Patient is currently dependent on oral corticosteroids for the treatment of asthma and the patient's asthma worsens upon tapering of oral corticosteroid therapy: **AND**

    Note: Examples of anti-interleukin therapies include Fasenra, Cinqair and Nucala.
7. Fasenra will be used in combination with one of the following:
    a. One high dose (appropriately adjusted for age) combination inhaled

corticosteroid (ICS)/long-acting beta2 agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; **OR**

b. Combination therapy including both of the following:
   - One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]; **AND**
   - One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

Continuation Therapy

1. The patient has already received at least 6 months of therapy with Fasenra; **AND**
   Note: Patients who have received < 6 months of therapy or those who are restarting therapy with Fasenra should be considered new to therapy – see above criteria.
2. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
3. The patient has responded to Fasenra therapy as determined by the prescriber.
   Note: Examples of a response to Fasenra therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department (ED)/urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value
2. Treatment of other eosinophilic conditions
3. The relief of acute bronchospasm or status asthmaticus
4. Coadministration with any of the following:
   a. Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Nucala (mepolizumab)]
   b. Anti-IgE therapy [e.g., Xolair (omalizumab)]
   c. Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)]

BACKGROUND

Fasenra (benralizumab) is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

Fasenra is a humanized monoclonal antibody that directly binds to human interleukin-5 receptor. The IL-5 receptor is expressed on the surface of eosinophils and basophils which are involved in inflammation, an important component in the pathogenesis of asthma. By binding to the IL-5Rα chain, benralizumab reduces eosinophils through antibody-dependent cell-mediated cytotoxicity.

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DEFINITIONS

1. FASENRA (benralizumab) injection, for subcutaneous use. Initial U.S. Approval: 2017
    a. FASENRA (benralizumab) injection is a sterile, preservative-free, clear to opalescent, colorless to slightly yellow solution and may contain a few translucent or white to off-white particles, for subcutaneous injection supplied as a single-dose prefilled syringe or single-dose autoinjector.

CODING

Applicable NDC Codes	
0310-0173-30	Fasenra 30mg single-dose prefilled syringe for injection
00310-1830-30	Fasenra 30mg single-dose prefilled pen injector

Applicable Procedure Code	
J0517	Injection, benralizumab, 1 mg

Applicable ICD-10 Codes	
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation

EVIDENCE BASED REFERENCES

1. Fasenra [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; September 2019. Accessed April 2021.

POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. February 22, 2022: Annual review – no changes made. February 28, 2023 – Annual Review and approval (no policy revisions made) March 1, 2023 – Adopted by MA UM Committee (no policy revisions made) January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics 2/28/2023