Benralizumab (Fasenra®)
Prior Authorization Criteria
Drug Protocol Management
MassHealth/Commercial/Exchange

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS:

Fasenra (benralizumab) is an interleukin-5 receptor alpha-directed cytolytic monoclonal antibody (IgGI, kappa) indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype. Fasenra (benralizumab) is not for treatment of other eosinophilic conditions and not for relief of acute bronchospasm or status asthmaticus.

POLICY

AllWays Health Partners may authorize coverage of Fasenra for members when ALL the following criteria are met:

1. The member has a documented diagnosis of severe eosinophilic asthma
2. The member is 12 years of age or older
3. The member is not an active smoker
4. The prescriber is an asthma specialist (e.g., allergist, immunologist, pulmonologist)
5. The member has a pre-treatment serum eosinophil count of ≥150 cells/mcL at screening (within the past 6 weeks prior to initiation of the requested agent)
6. Member has been adherent and maintained on high-dose inhaled corticosteroids (ICS) (at least 880 mcg/day, plus a long-acting beta agonist LABA, plus one other daily controller medication (e.g. leukotriene modifier) for at least 6 months prior to adding Fasenra and remain on controller medications during Fasenra treatment. **See Appendix A**
7. Clinical documentation of poor asthma control, despite adherence to controller medications, as defined by at least 2 of the following within that past 12 months:
    a. Two or more exacerbations requiring bursts of oral corticosteroid therapy
    b. At least 1 serious asthma exacerbation requiring hospitalization or and emergency department visit.
    c. Airflow limitation (FEV1 less than 80% of predicted)
    d. Poor symptom control (ACQ more than 1.5; ACT less than 20) which includes but not limited to clinical documentation of limitation of daily activities, nighttime awakening or dyspnea
    e. Persistent eosinophilic inflammation in the blood (Historical level of at least 300 cells/microliter in the last 15 months if it is documented that the patients is currently on oral steroids.

LIMITATIONS OF COVERAGE:

1. The member will not receive Fasenra in combination with another interleukin 5 (IL-5) inhibitor indicated for asthma (e.g., Cinqair, Nucala).
2. Other causes of eosinophilia such as hypereosinophilic syndromes, neoplastic disease, or parasitic disease must be ruled out.

Approval Duration: For maintenance treatment of severe asthma:

A. Initial authorization of Fasenra may be provided for six months.
B. Reauthorization of Fasenra may be provided for 12 months for members who have met the initial criteria AND with clinical documentation that the member has achieved and maintained a clinical response to Fasenra by two or more of the following:
    a. Increase in percent predicted (FEV1) from baseline (pretreatment)
    b. Reduction in asthma exacerbations (e.g., decreased frequency of use of unscheduled emergency departments and/or hospitalizations)
    c. Reduction in the use of oral corticosteroids to treat exacerbations and asthma symptoms such as chest tightness, coughing, shortness of breath, or nighttime awakenings

Annual reauthorization requires clinical documentation that the patient has been seen and evaluated within the previous 14 months and there is continued documented benefit from using Fasenra.

APPENDIX A: Comparative Dosing of Inhaled Corticosteroids

Medication	Adult Daily Doses
Beclomethasone MDI	>480 mcg
Budesonide DPI	>1,080 mcg
Ciclesonide MDI	>640 mcg
Flunisolide MDI	>640 mcg
Fluticasone MDI	>440 mcg
Fluticasone DPI	>500 mcg
Mometasone DPI	>440 mcg

References

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2. Brinke A, Sterk PJ, Masclee AA, et al. Risk factors of frequent exacerbations in difficult-to-treat asthma. Eur Respir J 2005; 26:812. (UpToDate)
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