Medical Policy:

Fasenra® (benralizumab) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.229	March 4, 2024	2017

Definitions

Fasenra, an interleukin-5 receptor alpha (IL-5Rα)-directed cytolytic monoclonal antibody, is indicated for severe asthma as add-on maintenance treatment of patients ≥ 12 years of age who have an eosinophilic phenotype.
Limitations of Use: Fasenra is not indicated for the treatment of other eosinophilic conditions or for the relief of acute bronchospasm/status asthmaticus.

Length of Authorization

Initial- 6 months
Continuation- 12 months

Dosing Limits [Medical Benefit]

Approve the following dosing regimens (A or B):

A. 30 mg administered subcutaneously once every 4 weeks for the first 3 doses; **OR**
B. 30 mg administered subcutaneously once every 8 weeks.

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

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

Guideline

1. **Asthma.** Approve Fasenra for the duration noted if the patient meets one of the following conditions (A or B):
   A. Initial Therapy. Approve for 6 months if the patient meets the following criteria (i, ii, iii, iv, and v):
      i. Patient is ≥ 12 years of age; **AND**
      ii. Patient has a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with Fasenra or another monoclonal antibody therapy that may lower blood eosinophil levels; **AND**
      Note: Examples of monoclonal antibody therapies that may lower blood eosinophil levels include Fasenra, Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous infusion), Dupixent (dupilumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
      iii. Patient has received at least 3 consecutive months of combination therapy with BOTH of the following (a and b):
         a. An inhaled corticosteroid; **AND**
         b. At least one additional asthma controller or asthma maintenance medication; **AND**
      Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and monoclonal antibody therapies for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire, Xolair). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfil the requirement for both criteria a and b.
      iv. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by ONE of the following (a, b, c, d, or e):
      Note: "Baseline" is defined as prior to receiving Fasenra or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Fasenra, Cinqair, Dupixent, Nucala, Tezspire, and Xolair.
         a. Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
         b. Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; **OR**
         c. Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**
         d. Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **OR**
         e. Patient has asthma that worsens upon tapering of oral (systemic) corticosteroid therapy; **AND**
      v. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
   B. Patient is Currently Receiving Fasenra. Approve for 1 year if the patient meets the following criteria (i, ii, and iii):
      i. Patient has already received at least 6 months of therapy with Fasenra; **AND**
      Note: A patient who has received < 6 months of therapy or who is restarting therapy with Fasenra should be considered under criterion 1A (Asthma, Initial Therapy).
      ii. Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**
      iii. Patient has responded to 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, urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

Conditions Not Recommended for Approval

Coverage of Fasenra is not recommended in the following situations:

1. Chronic Obstructive Pulmonary Disease (COPD)
2. Concurrent use of Fasenra with another Monoclonal Antibody Therapy (i.e., Cinqair, Nucala, Dupixent, Tezspire, Xolair, or Adbry)
3. Hypereosinophilic Syndrome

Applicable Procedure Codes

Code	Description
J0517	Injection, benralizumab, 1 mg

Applicable NDCs

Code	Description
00310-1730-85	Fasenra 30mg/mL Solution Prefilled Syringe
00310-1730-30	Fasenra 30mg/mL Solution Prefilled Syringe

ICD-10 Diagnoses

Code	Description
J45.50	Severe persistent asthma, uncomplicated
J82.81	Eosinophilic pneumonia, NOS
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/4/2024	Annual Review: No criteria changes. Updated Jcodes, removed J45.909, added J45.50, J82.81, J82.82, J82.83, J82.89. Updated dosing limits.
EmblemHealth & ConnectiCare	04/10/2023	Transfer from CCUM template to CoBranded Medical Template Retired MG.MM.PH.44
EmblemHealth & ConnectiCare	03/22/2023	Annual Revision: Conditions not recommended for approval: Criteria were updated to clarify that use of Fasenra with another monoclonal antibody therapy is specific to Cinqair, Nucala, Dupixent, Tezspire, Xolair, and Adbry.
EmblemHealth & ConnectiCare	07/20/2022	Asthma: Criteria for a blood eosinophil level ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to any anti-interleukin-5 therapy was changed to prior to any treatment with Cinqair or another monoclonal antibody therapy that may lower blood eosinophil levels. Throughout criteria, updated notes to include examples of monoclonal antibody therapies to include Dupixent (dupilumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), Adbry (tralokinumab-

		ldrm subcutaneous injection), and Xolair (omalizumab subcutaneous injection). Criteria requiring the patient to have experienced one or more asthma exacerbation(s) requiring a hospitalization or an emergency department visit in the previous year, were updated to include an urgent care visit as well. Conditions Not Recommended for Approval: Criteria were updated to recommend against use of Fasenra with another monoclonal antibody therapy. Previously, criteria listed anti-interleukin monoclonal antibody therapies and Xolair separately.
EmblemHealth & ConnectiCare	03/16/2022	Annual Revision: No criteria changes

References

1. Fasenra® subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca; October 2019.