Medical Policy:

Fasenra® (benralizumab) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.229	October 15, 2024	2017

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 ≥ 6 years of age who have an eosinophilic phenotype.
Limitations of Use: Fasenra is not indicated for the relief of acute bronchospasm/status asthmaticus.
Fasenra is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

Length of Authorization

Initial- 6 months
Continuation- 12 months

Dosing Limits [Medical Benefit]

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

Severe Asthma

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

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

− 30 billable units every 28 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 ≥ 6 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; **OR** the patient is dependent on systemic corticosteroids; **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, 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.

2. **Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome †**

Initial Criteria:

A. Patient is at least 18 years of age; **AND**

B. Patient has a confirmed diagnosis of EGPA§ (aka Churg-Strauss Syndrome); **AND**

C. Patient has relapsing or refractory disease; **AND**
D. Patient has received prior treatment with oral corticosteroids with or without immunosuppressive therapy; **AND**
E. Patient has been on a stable dose of oral corticosteroid therapy for at least 4 weeks prior to starting treatment; **AND**
F. Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Birmingham Vasculitis Activity Score [BVAS], history of asthma symptoms and/or exacerbations, duration of remission, or rate of relapses, etc.)

§Eosinophilic Granulomatosis Polyangiitis (EGPA) defined as all of the following:
• History or presence of asthma • Blood eosinophil level > 10% or an absolute eosinophil count >1000 cells/mm3 • Two or more of the following criteria: − Histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil rich granulomatous inflammation − Neuropathy − Pulmonary infiltrates − Sinonasal abnormalities − Cardiomyopathy − Glomerulonephritis − Alveolar hemorrhage − Palpable purpura − Antineutrophil Cytoplasmic Antibody (ANCA) positivity

Renewal:
A. Patient continues to meet the universal and other indication-specific relevant criteria identified in Initial Criteria; **AND**
B. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include:parasitic (helminth) infection, severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, urticaria, rash), etc.; **AND**
C. Disease response as indicated by improvement in signs and symptoms compared to baseline as evidenced by **ONE** or more of the following:
   i. Patient is in remission [defined as Birmingham Vasculitis Activity Score (BVAS)=0 (no active vasculitis) plus prednisolone/prednisone dose ≤7.5 mg/day or equivalent]
   ii. Decreased frequency in the occurrence of relapses
   iii. Decrease in the daily oral corticosteroid dose
   iv. Improvement on a disease activity scoring tool [e.g., Vasculitis Damage Index (VDI), Birmingham Vasculitis Activity Score (BVAS), Forced vital capacity (FVC), Forced Expiratory Volume during first second (FEV1), Asthma Control Questionnaire (6-item version) (ACQ-6), etc.]

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
00310-1745-01	Fasenra 10mg/0.5mL Solution Prefilled Syringe
00310-1830-30	Fasenra Pen 30mg/mL Solution Auto-injector

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
M30.1	Polyarteritis with lung involvement [Churg-Strauss]

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	10/15/20024	Revision: updated definition to include new indication. Added eosinophilic granulomatosis with polyangiitis (EGPA) indication and criteria- initial and renewal. Updated ICD-10 code and dosing limits
EmblemHealth & ConnectiCare	6/13/2024	Revision: Initial Criteria: Asthma: Removed leukotriene receptor antagonists as an example of additional asthma controller or asthma maintenance medications; added NDC 00310-1745-01 and 00310-1830-30
EmblemHealth & ConnectiCare	4/16/2024	Update: Initial Criteria: Asthma: added:" **OR** the patient is dependent on systemic corticosteroids;" to the following statement: "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; **OR** the patient is dependent on systemic corticosteroids;" Updated age in asthma from ≥ 12 years of age to ≥ 6 years of age.
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.