Medical Policy: `

Fasenra® (benralizumab) subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.229	April 21, 2025	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 ≥ 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

Initial Approval Criteria:

Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
All target agents are eligible for continuation of therapy

        1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**
        2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR**
    B. Both of the following:
        1. ONE of the following:
            A. The patient has a diagnosis of severe eosinophilic asthma and ALL of the following:
                1. The patient's diagnosis has been confirmed by ONE of the following:
                    A. The patient has a baseline (prior to therapy with the requested agent) blood eosinophil count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
                    B. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **OR**
                    C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **AND**
                2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:
                    A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**
                    B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**
                    C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**
                    D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**
            B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:
                1. The requested agent is FDA labeled or compendia supported for EGPA **AND**
                2. ONE of the following:
                    A. The patient has a baseline (prior to therapy for the requested indication) blood eosinophilia greater than or equal to 1000 cells/microliter **OR**
                    B. The patient has a baseline (prior to therapy for the requested indication) blood eosinophil level greater than or equal to 10%

eosinophils on white blood cell differential count **AND**

3. The patient has a history or presence of asthma **AND**
4. The patient does NOT have severe disease with organ- or lifethreatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia) **AND**
5. ONE of the following:
    A. BOTH of the following:
        1. The patient is currently treated within the past 90 days with oral corticosteroid (OCS) therapy for at least 4 weeks **AND**
        2. The patient will be using oral corticosteroid (OCS) therapy in combination with the requested agent **OR**
    B. The patient has an intolerance or hypersensitivity to therapy with an oral corticosteroid (OCS) **OR**
    C. The patient has an FDA labeled contraindication to ALL oral corticosteroids **AND**
6. The patient will be using the requested agent for ONE of the following:
    A. Treatment of relapsing/refractory disease **OR**
    B. Treatment for maintenance of disease remission **OR**

C. The patient has another FDA labeled indication for the requested agent and route of administration AND

2. If the patient has an FDA labeled indication, then ONE of the following:
    A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**
    B. There is support for using the requested agent for the patient's age for the requested indication **OR**

C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**

2. If the patient has a diagnosis of severe eosinophilic asthma, then ALL of the following:
    A. ONE of the following:
        1. The patient is NOT currently treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR**
        2. The patient is currently treated with the requested agent AND ONE of the following:
            A. The patient is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days **OR**
            B. The patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR**
        3. The patient has an intolerance or hypersensitivity to therapy with an inhaled corticosteroid **OR**
        4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND**
    B. ONE of the following:
        1. The patient is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following:
            A. A long-acting beta-2 agonist (LABA) **OR**
            B. A long-acting muscarinic antagonist (LAMA) **OR**
            C. A leukotriene receptor antagonist (LTRA) **OR**
            D. Theophylline **OR**
        2. The patient has an intolerance or hypersensitivity to therapy with a long-acting beta-2 agonist

(LABA), a long-acting muscarinic antagonist (LAMA), a leukotriene receptor antagonist (LTRA), or theophylline **OR**

3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND**

C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**

3. If the requested agent is Fasenra 30mg/mL prefilled syringe, then BOTH of the following:

Requested Agent	Self-Administered Trial Product(s)	Preferred Provider Administered Trial Product(s)
Fasenra 30 mg/mL prefilled syringe	Fasenra 30 mg/mL autoinjector pen	N/A

A. ONE of the following (reference table above):
   1. The patient has tried a self-administered trial product for the requested agent **OR**
   2. There is support for the use of a provider-administered product over self-administered products **AND**

B. ONE of the following (reference table above):
   1. The requested agent does NOT require a preferred provider-administered trial product **OR**
   2. The patient has tried a preferred provider-administered trial product for the requested agent **OR**
   3. There is support for the use of the requested agent over ALL preferred provideradministered trial products **AND**

4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
   A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
   B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:
      1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
      2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**
6. The patient does NOT have any FDA labeled contraindications to the requested agent AND
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Renewal Criteria:

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Medical Drug Review process [Note: patients not previously approved for the requested agent will require initial evaluation review] **AND**
2. ONE of the following:
   A. The patient has a diagnosis of severe eosinophilic asthma AND BOTH of the following:

1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
    A. Increase in percent predicted Forced Expiratory Volume (FEV1) **OR**
    B. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**
    C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR**
    D. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND**
2. The patient is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **OR**

B. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
    1. Remission achieved with the requested agent **OR**
    2. Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **OR**
    3. Decrease in hospitalization due to symptoms of EGPA **OR**
    4. Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **OR**

C. The patient has a diagnosis other than severe eosinophilic asthma, EGPA AND has had clinical benefit with the requested agent **AND**

3. If the requested agent is Fasenra 30mg/mL prefilled syringe, then BOTH of the following:

Requested Agent	Self-Administered Trial Product(s)	Preferred Provider Administered Trial Product(s)
Fasenra 30 mg/mL prefilled syringe	Fasenra 30 mg/mL autoinjector pen	N/A

    A. ONE of the following (reference table above):
        1. The patient has tried a self-administered trial product for the requested agent **OR**
        2. There is support for the use of a provider-administered product over self-administered products **AND**
    B. ONE of the following (reference table above):
        1. The requested agent does NOT require a preferred provider-administered trial product **OR**
        2. The patient has tried a preferred provider-administered trial product for the requested agent **OR**
        3. There is support for the use of the requested agent over ALL preferred provider-administered trial products **AND**
4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist, rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**
5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):
    The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR**
    A. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:

1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**
2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**

6. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
7. The requested quantity (dose) is within FDA labeled dosing (or supported in compendia) for the requested indication

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib)

Orencia (abatacept) Otezla (apremilast) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Remicade (infliximab) Renflexis (infliximab-abda) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Saphnelo (anifrolumab-fnia) Selarsdi (ustekinumab-aekn) Siliq (brodalumab) Simlandi (adalimumab-ryvk) Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection Stelara (ustekinumab) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tysabri (natalizumab) Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

Dosage/Administration

Indication	Dose
Severe Eosinophilic Asthma	**Adults and Adolescent Patients ≥ 12 Years of Age** Administer 30 mg (one injection) subcutaneously every 4 weeks for the first three doses and then once every 8 weeks thereafter. **Pediatric Patients 6 to 11 Years of Age (Body Weight Dosing)** • < 35 kg: 10 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.

	• ≥ 35 kg: 30 mg (one injection) administered subcutaneously every 4 weeks for the first 3 doses, and then every 8 weeks thereafter.
Eosinophilic Granulomatosis with Polyangiitis (EGPA)	Administer 30mg (one injection) subcutaneously every 4 weeks

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	04/21/2025	Annual Review: Revision to policy to separate initial/renewal/dosage criteria. Additional updates to clarify specific requirements for criteria review. Separated out “target agents” for specific formulation as well as criteria to reference the chart for review. Removed contraindication tab – replaced with contraindicated as concomitant therapy all of the agents that are NOT to be used concomitantly. Addition of chart for Dosage/Administration/Indication.
EmblemHealth & ConnectiCare	10/15/2024	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 [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; September 2024. Accessed April 2025