Fasenra® (benralizumab)
(Subcutaneous)

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I. Length of Authorization

- Initial: 6 months for severe eosinophilic asthma; 12 months for EGPA and all other indications
- Renewal: 12 months for all indications

II. Dosing Limits

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

- **Severe Eosinophilic 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

III. Initial Approval Criteria

- Patients must have an inadequate response to an adequate trial of, or contraindication or intolerance to at least two of the following: mepolizumab (Nucala®), dupilumab (Dupixent®), tezepelumab-ekko (Tezspire®), and/or omalizumab (Xolair®); **AND**

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 life-threatening 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. 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**
4. 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**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. 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

IV. 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. 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**
4. 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**
5. The patient does NOT have any FDA labeled contraindications to the requested agent **AND**
6. 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)

Contraindicated as Concomitant Therapy
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)

Contraindicated as Concomitant Therapy
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)

V. 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 30 mg (one injection) subcutaneously every 4 weeks

VI. Billing Code/Availability Information

HCPCS Code:

- J0517 – Injection, benralizumab, 1 mg; 1 billable unit = 1 mg

NDC(s):

- Fasenra 10 mg/0.5 mL single-dose prefilled syringe: 00310-1745-xx
- Fasenra 30 mg/mL single-dose prefilled syringe: 00310-1730-xx
- Fasenra 30 mg/mL single-dose autoinjector FASENRA PEN: 00310-1830-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD,

or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC