Fasenra®
(benralizumab) Subcutaneous injection 30 mg
AstraZeneca
Access 360™
FASENRA
PRIOR AUTHORIZATION (PA)
CONSIDERATIONS

Prior Authorization (PA) Considerations for Severe Eosinophilic Asthma

Fasenra® (benralizumab) Subcutaneous Injection | AstraZeneca Access 360™

FASENRA is indicated for:

- the add-on maintenance treatment of patients with severe asthma aged 6 years and older and with an eosinophilic phenotype. FASENRA is not indicated for the relief of acute bronchospasm or status asthmaticus

Limitations of use: Not for relief of acute bronchospasm or status asthmaticus.

FASENRA coverage criteria may differ across insurance payers. Providing accurate and complete clinical documentation in support of the provider's treatment decision is key to timely review of PA requests and appeals. Payers may require different clinical notes for initiation of therapy vs continuation of therapy.

Is the patient NEW to FASENRA therapy? —or— Continuing therapy with FASENRA?

Diagnosis

Was FASENRA prescribed in accordance with the FDA-approved labeling?

- ☐ Please refer to the **Prescribing Information**
- ☐ Is the patient 6 years of age or older?
- ☐ Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype?
- ☐ Was FASENRA prescribed as an add-on maintenance therapy for treatment of severe asthma?

Does the payer require submission of the patient's current blood eosinophil count (complete blood count (CBC) with differential)?

- ☐ Payers may require baseline blood eosinophil count (eg, ≥150 cells/µL) and some may require CBC with differential and some may require a historical CBC with differential
- ☐ Consider documenting or including a letter of medical necessity if other medications (eg, prednisone) and/or medical conditions decreased the patient's blood eosinophil count to <150 cells/µL

Disease History

Has the patient experienced poor asthma control, despite optimized doses of inhaled corticosteroid (ICS)/long-acting β-agonist (LABA)?

- ☐ Use of systemic corticosteroids
- ☐ Emergency room visits
- ☐ Urgent care or unplanned medical provider visits for nebulizer or other urgent asthma treatment
- ☐ Hospitalizations
- ☐ Other _____

Has the patient had spirometry or a pulmonary function test (PFT) at baseline?

- ☐ Does the patient have reduced lung function?
  - — Some payers may require documentation of the patient's PFTs at baseline—some payers may require pre- and post-spirometry results

Treatment Factors

Does the patient have inadequate asthma control despite current treatment?

- ☐ Maximally dosed ICS with additional asthma controller medications (LABA, long acting muscarinic antagonist (LAMA), leukotriene modifier, sustained release theophylline, etc)
- ☐ Maximally dosed combination ICS/LABA product

Document the names of any previous and current asthma medications including length of therapy for each one

Was FASENRA prescribed by or in consultation with an allergist, immunologist or pulmonologist?

Consider submitting additional documentation (ie, letter of medical necessity, clinical notes) to support the prior authorization request

Continuation of Therapy/ Reauthorization Criteria

Is the patient still using maintenance asthma medications in addition to receiving FASENRA?

Treatment with FASENRA has resulted in one or more of the following:

- ☐ Decreased utilization of rescue medications; OR
- ☐ Decreased frequency of exacerbations
- ☐ Increase in percent predicted FEV_1 from pretreatment baseline; OR
- ☐ Reduction in reported asthma-related symptoms (eg, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing)

For patients switching insurance, new payers may require initial clinical documentation from previous payer

Visit the FASENRA Policy Acumen Portal to access Payer billing, coding, and coverage policy resources **https://fasenra.policyacumen.health**

Labs may report eosinophils in different units of measure. To convert to cells/µL, our eosinophil calculator is available at **www.fasenrahcp.com**

Click **here** to download the FASENRA Access and Reimbursement Guide

Please read additional Important Safety Information throughout and full Prescribing Information, including Patient Information.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to benralizumab or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, anaphylaxis, angioedema, urticaria, rash) have occurred after administration of FASENRA. These reactions generally occur within hours of administration, but in some instances have a delayed onset (ie, days). Discontinue in the event of a hypersensitivity reaction.

Acute Asthma Symptoms or Deteriorating Disease

FASENRA should not be used to treat acute asthma symptoms, acute exacerbations, or acute bronchospasm.

Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with FASENRA. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

It is unknown if FASENRA will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with FASENRA. If patients become infected while receiving FASENRA and do not respond to anti-helminth treatment, discontinue FASENRA until infection resolves.

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Common Severe Eosinophilic Asthma Terms:

Blood eosinophil count: a blood test that measures the number of one type of white blood cells called eosinophils

CBC with differential: a blood test that measures many different parts and features of your blood

Eosinophilic phenotype: a distinct phenotype of severe asthma, which includes increased levels of eosinophils in the blood and airways

Exacerbation: worsening with increase in the severity of a disease or its signs and symptoms

Forced Expiratory Volume (FEV): volume of air exhaled in the first second under force after a maximal inhalation

Inhaled corticosteroid (ICS): reduces airway inflammation. For adults and children with asthma, ICS-containing controller treatment is essential to reduce exacerbation risk and control symptoms

Leukotriene receptor antagonist (LTRA): initial controller treatment for patients unable/unwilling to use ICS, patients with intolerable ICS-related side effects, or patients with concomitant allergic rhinitis

Long-acting β–agonist (LABA): bronchodilators; used as control or maintenance medication

Long-acting muscarinic agonist (LAMA): bronchodilators; used as control or maintenance medication

Pulmonary Function Test (PFT): used to diagnose various respiratory diseases and assess lung function (eg, spirometry)

Spirometry: a basic pulmonary function test that measures how much and how fast air moves out of the lungs

Systemic corticosteroid: a highly effective treatment for acute exacerbations and long-term symptom control in asthma

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Not an actual patient.

Prior Authorization (PA) Considerations for Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Fasenra® (benralizumab) Subcutaneous Injection | AstraZeneca Access 360™

FASENRA is indicated for:

- treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

Limitations of Use: Not for relief of acute bronchospasm or status asthmaticus.

FASENRA coverage criteria may differ across insurance payers. Providing accurate and complete clinical documentation in support of the provider's treatment decision is key to timely review of PA requests and appeals. Payers may require different clinical notes for initiation of therapy versus continuation of therapy.

Is the patient NEW to FASENRA therapy? —or— Continuing therapy with FASENRA?

Diagnosis

Was FASENRA prescribed in accordance with the FDA-approved labeling?

- ☐ Please refer to the **Prescribing Information**
- ☐ Is the patient 18 years or older?
- ☐ Does the patient have a diagnosis of eosinophilic granulomatosis with polyangitis (EGPA)?

Disease History

Has the patient had relapses or refractory disease over the past two years (ie, requiring increase in oral corticosteroid dose, initiation or increase in dose of immunosuppressive therapy or hospitalization)?

Does the payer require submission of the patient's current or historical blood eosinophil count (complete blood count (CBC) with differential)?

- ☐ Payers may require baseline blood eosinophil level of at least 10% of leucocytes or an absolute eosinophil count >1,000 cells/µL
- ☐ Consider documenting or including a letter of medical necessity if other medications (eg, prednisone) and/or medical conditions decreased the patient's blood eosinophil count

Does the patient have at least two characteristics typical of EGPA (ie, sino-nasal abnormality, pulmonary infiltrates, non fixed, neuropathy, mono or poly)?*†

Treatment Factors

Is the patient currently taking oral corticosteroids?

- ☐ Systemic glucocorticoids (eg, prednisone, methylprednisone)
- ☐ With or without immunosuppressive therapy (eg, cyclophosphamide, rituximab, azathioprine, mycophe-nolate mofetil, methotrexate)

Was FASENRA prescribed by or in consultation with an allergist/ immunologist, rheumatologist or pulmonologist?

Consider submitting additional documentation (ie, letter of medical necessity, clinical notes, FDA approval letter, full Prescribing Information) to support the prior authorization request

Continuation of Therapy/ Reauthorization Criteria

Member continues to have a beneficial response to treatment with the requested medication as demonstrated by any of the following:

- ☐ A reduction in the frequency of or severity of relapses; OR
- ☐ A reduction or discontinuation of daily oral corticosteroid dose and/or immunosuppressive therapy; OR
- ☐ No active vasculitis
- ☐ Reduction in severity; OR frequency of EGPA-related symptoms

For patients switching insurance, new payers may require initial clinical documentation from previous payer

*See Common EGPA Terms on next page for definition

†A biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophil-rich granulomatous inflammation is commonly used

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IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥ 5%) include headache and pharyngitis.

Injection site reactions (eg, pain, erythema, pruritus, papule) occurred at a rate of 2.2% in patients treated with FASENRA compared with 1.9% in patients treated with placebo in asthma exacerbation studies.

USE IN SPECIFIC POPULATIONS

The data on pregnancy exposure from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

INDICATIONS

FASENRA is indicated for:

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- the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA)

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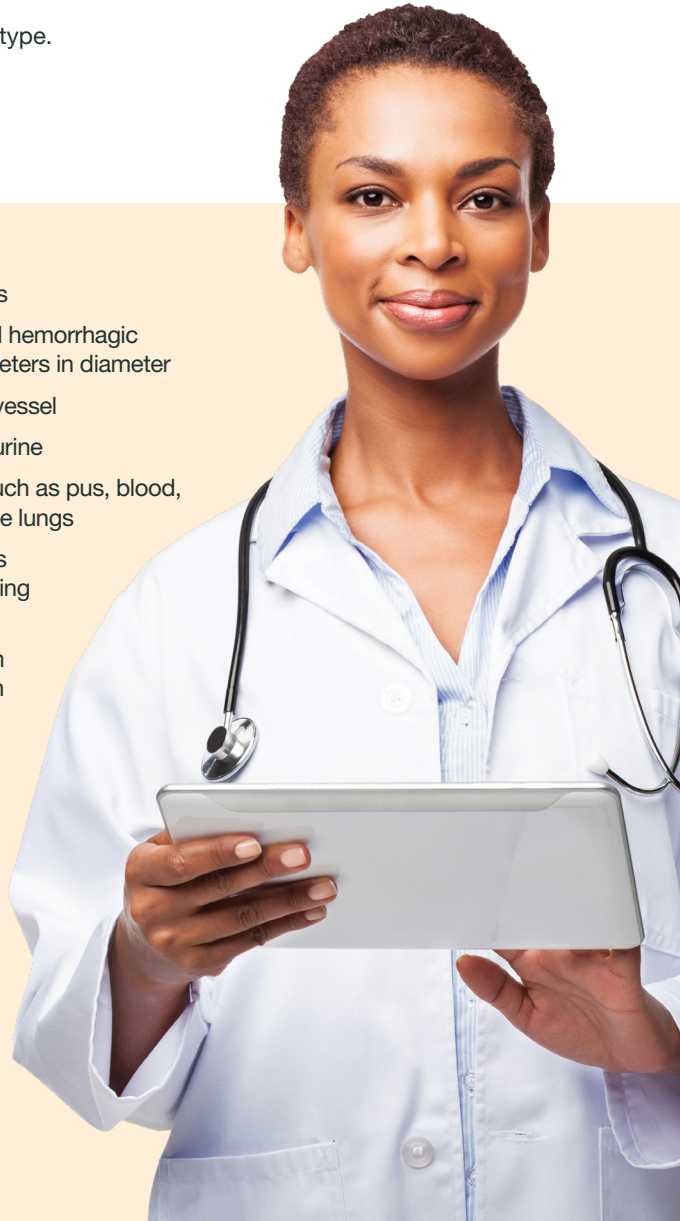

Common EGPA Terms:

Alveolar hemorrhage: is persistent or recurrent pulmonary hemorrhage that originates from the lung parenchyma (ie, the alveoli) as opposed to the airways

Anti-neutrophil cytoplasmic anti-body (ANCA) positive (myeloperoxidase or proteinase): a group of autoantibodies, mainly of the IgG type, against antigens in the cytoplasm of neutrophils and monocytes. They are detected as a blood test in a number of autoimmune disorders, but are particularly associated with systemic vasculitis

Bronchoalveolar lavage: also known as bronchoalveolar washing, is a diagnostic method of the lower respiratory system in which a bronchoscope is passed through the mouth or nose into an appropriate airway in the lungs, with a measured amount of fluid introduced and then collected for examination

Cardiomyopathy: group of primary diseases of the heart muscle

EGPA: is a form of vasculitis that affects the small blood vessels. EGPA can affect the lungs, sinuses, skin, heart, intestinal tract, kidneys, nerves, and other organs. Formerly called Churg Strauss syndrome, EGPA is one of the rarest forms of vasculitis

Glomerulonephritis: is a term used to refer to several kidney diseases (usually affecting both kidneys)

Granulomatous inflammation: is a histologic pattern of tissue reaction which appears following cell injury

Hematuria: the presence of blood or red blood cells in the urine

Immunosuppressive therapy: drugs that inhibit or prevent the activity of the immune system (ie, azathioprine, cyclophosphamide, mycophenolate mofetil, methotrexate, rituximab)

Neuropathy: damage or disease affecting the nerves

Palpable purpura: is characterized by firm, elevated hemorrhagic plaques or papules that can measure several centimeters in diameter

Perivascular: situated or occurring around a blood vessel

Proteinuria: the presence of excess proteins in the urine

Pulmonary infiltrates: substance denser than air, such as pus, blood, or protein, which lingers within the parenchyma of the lungs

Red cell casts: is a type of urinary cast that contains erythrocytes (red blood cells). It is indicative of bleeding within the kidney

Refractory disease: failure to attain remission within the prior 6 months following induction treatment with standard regimens

Remission (EGPA): the absence of clinical signs or symptoms attributable to active disease

Rhinosinusitis: is a simultaneous infection of the nasal mucosa and an infection of the mucosa of the paranasal sinuses

Sino-nasal abnormality: abnormal finding in the nasal cavity and paranasal sinuses

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Please see full Prescribing Information, including Patient Information.

You may report side effects related to AstraZeneca products.

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