AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Fasenra® SQ (benralizumab) **(Pharmacy)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

Recommended Dosing:

- ❑ **Asthma, severe eosinophilic:**
  - **Adult and Adolescent Patients 12 Years of Age and Older:**
    - 30 mg every 4 weeks for the first 3 doses followed by once every 8 weeks thereafter
  - Pediatric Patients 6 Years to 11 Years of Age:
    - Weighing Less Than 35 kg: the recommended dosage is 10 mg every 4 weeks for the first 3 doses followed by once every 8 weeks thereafter
    - Weighing 35 kg or More: the recommended dosage is 30 mg every 4 weeks for the first 3 doses followed by once every 8 weeks thereafter
- ❑ **Eosinophilic granulomatosis with polyangiitis (EGPA):** 30 mg every 4 weeks
- ❑ **Hypereosinophilic syndrome (HES):** 30 mg every 4 weeks

Quantity Limits: 1 syringe per 56 days (both strengths)

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Medication will be (select ONE of the following):

- ❑ **Self-Administered** (pharmacy benefit)
- ❑ **Administered by Provider** (medical benefit)

***The Health Plan considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, Tezspire™ and Xolair® to be experimental and investigational. Safety and efficacy of these combinations have NOT been established and will NOT be permitted. In the event a member has an active Cinqair®, Dupixent®, Nucala®, Tezspire™ or Xolair® authorization on file, all subsequent requests for Fasenra® will NOT be approved.**

- Will the member be discontinuing a previously prescribed biologic if approved for requested medication?
  ❑ Yes **OR** ❑ No
- If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

  Medication to be discontinued: _____ **Effective date:** _____

  Medication to be initiated: _____ **Effective date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Asthma, severe eosinophilic**

Initial Authorization: 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist or pulmonologist
- ❑ Member is 6 years of age or older
- ❑ Has the member been approved for Fasenra® previously through the AvMed medical department?
  ❑ Yes ❑ No
- ❑ Member has been diagnosed with severe eosinophilic phenotype defined by a baseline (pre-Fasenra®) peripheral blood eosinophil level ≥ 150 cells/microliter at the initiation of treatment
- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications and must be compliant on therapy **for at least 90 consecutive days** within a year of request **(verified by pharmacy paid claims)**:
  - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - ❑ One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))

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- ❑ Member has experienced **ONE** of the following (check box that applies):
  - ❑ **ONE (1)** or more exacerbations requiring additional medical treatment (e.g., oral corticosteroids, emergency department, urgent care visits or hospitalizations within the past 12 months)
  - ❑ Any prior intubation for an asthma exacerbation
- ❑ Member has a baseline forced expiratory volume (FEV1) < 80% predicted normal (< 90% for members 12-17 years old) submitted within year of request
- ❑ Provider must submit member blood eosinophil count after a trial and failure of at least 90 consecutive days of therapy with high dose inhaled corticosteroids **AND** long-acting inhaled beta-2 agonist. A failure of these medications is defined as a blood count > 150 cells/microliter **(submit labs collected within the past 12 months)**

Eosinophil count: _____ **Date:** _____

❑ Diagnosis: Asthma, severe eosinophilic

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced a sustained positive clinical response to Fasenra® therapy as demonstrated by at least **ONE** of the following **(check all that apply)**:
  - ❑ Increase in percent predicted Forced Expiratory Volume (FEV1) from baseline (pre-treatment)
  - ❑ Reduction in the dose of inhaled corticosteroids required to control asthma
  - ❑ Reduction in the use of oral corticosteroids to treat/prevent exacerbation
  - ❑ Reduction in asthma symptoms such as chest tightness, coughing, shortness of breath or nocturnal awakenings
- ❑ Member is currently being treated with **ONE** of the following unless there is a contraindication or intolerance to these medications **(verified by pharmacy paid claims)**:
  - ❑ High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day) **AND** an additional asthma controller medication (e.g., leukotriene receptor antagonist, long-acting beta-2 agonist (LABA), theophylline)
  - ❑ One maximally dosed combination ICS/LABA product (e.g., Advair® (fluticasone propionate/salmeterol), Dulera® (mometasone/formoterol), Symbicort® (budesonide/formoterol))

❑ Diagnosis: Eosinophilic Granulomatosis Polyangiitis (EGPA)

Initial Authorization : 12 months

- ❑ Prescribed by or in consultation with an allergist, immunologist, pulmonologist, or rheumatologist
- ❑ Member is 18 years of age or older

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- ❑ Has the member been approved for Fasenra® previously through the AvMed medical department?
  - ❑ Yes ❑ No
- ❑ Member must have a diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) based on the history or presence of asthma
- ❑ Member must have a blood eosinophil level > 10% of total white blood cells or an absolute eosinophil count > 1000 cells/mm^3 at baseline

  Eosinophil count: _____ Date: _____
- ❑ Member must have documentation of **TWO** of the following:
  - ❑ A biopsy showing histopathologic evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil rich granulomatous inflammation
  - ❑ Neuropath; mono-or polyneuropathy
  - ❑ Pulmonary infiltrates, non-fixed on chest x-rays
  - ❑ Sino-nasal abnormality
  - ❑ Magnetic Resonance Imaging or Echocardiography of cardiomyopathy
  - ❑ Glomerulonephritis
  - ❑ Alveolar hemorrhage (by bronchoalveloar lavage)
  - ❑ Palpable purpura
  - ❑ Anti-neutrophil cytoplasmic anti-body (ANCA) positive or (Myeloperoxidase or proteinase 3)
- ❑ 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.)
- ❑ Member has active, non-severe disease defined as vasculitis without life-or organ-threatening manifestations. **Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease and mild inflammatory arthritis.**
- ❑ Member must have a history of **ONE** of the following:
  - ❑ **Relapsing disease:**
    - ❑ Member must have a history of at least **ONE** confirmed EGPA relapse requiring:
      - ❑ An increase in oral corticosteroids (OCS) dose
      - ❑ Initiation or increased dose of immunosuppressive therapy (e.g., azathioprine, cyclophosphamide, methotrexate, or mycophenolate mofetil, rituximab)
      - ❑ Hospitalization
    - ❑ Must have occurred within the past 2 years while receiving a dose of prednisone (or equivalent) of > 7.5 milligram per day (mg/day) for **at least 90 consecutive days**

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- ❑ **Refractory disease:**
  - ❑ Refractory disease must meet **ONE** of the following:
    - ❑ Failure to attain remission (Birmingham Vasculitis Activity Score (BVAS) =0) and OCS dose < 7.5 mg/day prednisone or equivalent) for **at least 90 consecutive days** within the last 6 months following a standard regimen **(**e.g., azathioprine cyclophosphamide, methotrexate, mycophenolate mofetil, high-dose corticosteroids or rituximab administered for at least 3 months
    - ❑ Within the past 6 months, the member has had a recurrence of EGPA symptoms during the tapering of oral corticosteroids (OCS), at any dose level of ≥ 7.5 mg/day of prednisone or equivalent, taken for **at least 90 consecutive days**
- ❑ Member has been on a stable dose of oral corticosteroid therapy for at least 4 weeks prior to starting treatment (e.g., prednisone or equivalent of ≥ 7.5 mg/day)

❑ Diagnosis: Eosinophilic Granulomatosis Polyangiitis (EGPA)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member must meet **ONE** of the following:
  - ❑ Documentation of remission or improvement in the Birmingham Vasculitis Activity Score (BVAS)=0 (no active vasculitis) plus prednisone/prednisolone daily dose of ≤ 7.5 mg/day or equivalent
  - ❑ Documentation of improvement in duration of remission or decrease frequency in the occurrence of relapses
  - ❑ Documentation of decrease in maintenance dose of systemic corticosteroids
  - ❑ Documentation of 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.]

❑ Diagnosis: Hypereosinophilic Syndrome (HES)

Initial Authorization : 12 months

- ❑ Member is ≥ 12 years of age
- ❑ Prescriber is or has consulted with an Allergist, Immunologist, Pulmonologist or Rheumatologist
- ❑ Member has a diagnosis of HES for 6 months or longer without any non-hematologic secondary cause (i.e. drug hypersensitivity, parasitic helminth infection, human immunodeficiency virus infection, non-hematologic malignancy) **(submit chart notes and labs confirming diagnosis)**
- ❑ Member has FIP1L1-PDGFRα-negative disease

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- ❑ Member has had two or more episodes of HES-related flares (worsening of clinical symptoms and/or worsening of blood eosinophil counts) requiring escalation of therapy in the past 12 months **(submit chart notes)**
- ❑ Member's HES-related flares occur spontaneously and did **NOT** occur within 4 weeks of a decrease in therapy
- ❑ Member has been on a stable dose of HES therapy (such as oral corticosteroids, immunosuppressive agents and/or cytotoxic therapy) for the past 4 or more weeks **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member's blood eosinophil count is ≥ 1000 cells/microliter while taking stable doses of HES therapy **(submit labs obtained within 4 weeks of request)**

❑ Diagnosis: Hypereosinophilic Syndrome (HES)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ❑ Member has experienced a positive response to Fasenra® therapy as determined by the prescriber (i.e. decreased number of flares, improved fatigue, reduced corticosteroid requirements, and decreased eosinophil levels) **(submit chart notes)**

Medication being provided by a Specialty Pharmacy – Proprium Rx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.*