

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

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 Health Plans 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 Health Plans 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/mm³ 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 bronchoalveolar 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.]

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.****