AvMed

MEDICAL 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 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Fasenra® SQ (benralizumab) (J0517) (Medical)

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 Name/Form/Strength: _____

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

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

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

☐ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

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

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❑ **Eosinophilic granulomatosis with polyangiitis (EGPA):** 30 mg every 4 weeks

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

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.**

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:
  - ❑ 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))
- ❑ Member has experienced **ONE** of the following (check box that applies):
  - ❑ More than > 2 exacerbations requiring additional medical treatment (e.g., an increase in oral corticosteroid dose, emergency department, urgent care visits or hospitalizations) within the past 12 months
  - ❑ Any prior intubation for an asthma exacerbation

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- ❑ 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; chart notes must be submitted)**:
  - ❑ 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:
  - ❑ 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
- ❑ Has the member been approved for Fasenra® previously through the Health Plan 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

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- ❑ 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, 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**
  - ❑ **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**

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- ❑ 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 ≤ 7.5mg/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 (check applicable box(es) below):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – Proprium Rx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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.****

***Approved by Pharmacy and Therapeutics Committee:** ~~2/15/2018; 3/17/2022;~~ **11/21/2024**
REVISED/UPDATED: ~~6/18/2018, 7/13/2018; 9/20/18; 12/31/2018; 3/21/2019; 7/6/2019; 9/16/2019, 3/31/2020; 4/26/2022; 6/16/2022; 6/29/2022;~~ **12/17/2024**