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: Tavneos™ (avacopan)

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

Quantity Limits: 180 capsules per 30 days

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: Severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA], formerly known as Wegener's granulomatosis, and microscopic polyangiitis [MPA])**

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Prescribed by or in consultation with a specialist in rheumatology, nephrology, or with a focus in treating patients with vasculitis

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- ❑ Member has a diagnosis of granulomatosis with polyangiitis (Wegener's) or microscopic polyangiitis and **ONE** of the following:
  - ❑ Tissue biopsy and histological documentation at the site of active disease
  - ❑ Results from antigen-specific enzyme-linked immunosorbent assays (ELISAs) or an indirect immunofluorescence (IIF) assay confirming auto-antibodies for proteinase 3 (PR3) or myeloperoxidase (MPO)]
- ❑ Provider has assessed disease severity utilizing the Birmingham Vasculitis Activity Score [BVAS]) and patient has a baseline score of ≥ 16 with **ONE** of the following:
  - ❑ At least 1 major item
  - ❑ At least 3 non-major items
  - ❑ At least the 2 renal items of proteinuria and hematuria
- ❑ Member has been evaluated and screened for the presence of hepatitis B virus (HBV) prior to initiating treatment
- ❑ Member does **NOT** have an active infection, including clinically important localized infections
- ❑ Member does **NOT** have severe hepatic impairment (e.g., Child-Pugh C) or active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis, cirrhosis)
- ❑ Provider attests member will avoid concomitant therapy with strong and moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's wort)
- ❑ Provider attests member will avoid concomitant therapy with CYP3A4 inhibitors (e.g., ketoconazole, itraconazole), or if therapy is unavoidable, member will be monitored closely for adverse reaction and/or dose modifications will be implemented
- ❑ Member has documentation of failed therapy to induce remission of AAV with **BOTH** of the following:
  - ❑ rituximab dosed at 375 mg/m^2 once weekly for 4 doses or 1 g once every 2 weeks for 2 doses, administered in combination with a systemic glucocorticoid
  - ❑ cylcophosphamide (IV: 600 mg/m^2 once every month; Oral: 2 mg/kg once daily) administered in combination with a systemic glucocorticoid for 3 to 6 months
- ❑ Member has documentation of failed therapy to achieve and sustain remission of AAV with **BOTH** of the following:
  - ❑ rituximab dosed at 500 mg once every 2 weeks for 2 doses, then 500 mg or 1 g once every 4 to 6 months. [**NOTE: medical history must confirm that maintenance dosing was given within 4 to 6 months of the last rituximab induction dose or if induction therapy was cyclophosphamide-based, begin rituximab maintenance therapy within 1 month following white blood cell recovery]**
  - ❑ methotrexate or azathioprine
- ❑ Medication will be used as adjunctive therapy in combination with standard therapy (e.g., corticosteroids, cyclophosphamide, azathioprine, mycophenolate, rituximab)

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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 is **NOT** experiencing any toxicity from therapy (e.g., hepatotoxicity, severe hypersensitivity reactions, serious infections)
- ❑ Member satisfies both induction and remission therapy requirements in the initial criteria section above
- ❑ Member has experienced a positive clinical response to therapy noted by **ALL** of the following:
  - ❑ Remission (defined as a composite scoring index of 0 on the BVAS)
  - ❑ Reduction in glucocorticoid requirement **(verified by chart notes or pharmacy paid claims)**
  - ❑ Submission of clinical documentation indicating stable or improved disease status (e.g., medical chart notes, laboratory documentation (ANCA levels, renal values), reduced flares, amelioration in organ manifestations)

Medication being provided by Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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.*