OPTIMA HEALTH PLAN

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 1-800-750-9692**. 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 may be delayed.**

Drug Requested: Tavneos™ (avacopan)

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

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
- ❑ 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

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- ❑ 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)

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)

(Continued on next page; signature page is required to process request.)

(Please ensure signature page is attached to form.)

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.****

Member Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee: 1/20/2022**
REVISED/UPDATED: ~~1/13/2022;~~ ~~2/23/2022;~~ **3/23/2022**