Pharmacy Policy Bulletin: J-1153 Tavneos (avacopan) – Commercial and Healthcare Reform	
Number: J-1153	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1153-004	**Original Date:** 12/01/2021
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Tavneos (avacopan)
FDA-Approved Indication(s):	• Adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

Background:	• Tavneos is a complement 5a receptor (C5aR) antagonist that inhibits the interaction between the C5aR and the complement peptide C5a. Tavneos blocks C5a-mediated neutrophil activation and migration. The mechanism by which Tavneos exerts its therapeutic effect in patients with ANCA-associated vasculitis has not been definitively established. • ANCA-associated vasculitis (AAV) is a group of rare autoimmune diseases (GPA, eosinophilic granulomatosis with polyangiitis [EGPA], and MPA). AAV occurs when ANCAs attach to neutrophils and cause destruction and inflammation of small vessels. There are fewer than 200,000 AAV patients in the United States. • GPA and MPA have been found to be strongly associated with ANCAs directed against either proteinase 3 (anti-PR3) or myeloperoxidase (anti-MPO). The Kidney Disease Improving Global Outcomes (KDIGO) guidelines recommend combining clinical presentation with positive PR3 or MPO ANCA serology to confirm diagnosis; waiting for a kidney biopsy should not delay starting immunosuppressive therapy. • Treatment of GPA and MPA is divided into two phases of treatment: induction and maintenance. The 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody–Associated Vasculitis recommends rituximab in combination with glucocorticoids for treatment of patients with active, severe GPA/MPA for induction of remission. For patients with active, non-severe disease, methotrexate in combination with glucocorticoids is recommended as initial

	treatment. Rituximab, methotrexate or azathioprine, and mycophenolate mofetil or leflunomide are recommended for maintenance of remission. • The 2024 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for the Management of ANCA–Associated Vasculitis recommend that glucocorticoids in combination with rituximab or cyclophosphamide be used as initial treatment of new-onset AAV. As a practice point, Avacopan may be used as an alternative to glucocorticoids. Patients with an increased risk of glucocorticoids toxicity are likely to receive the most benefit from avacopan. A post hoc analysis of patients with low glomerular filtration rate (GFR) suggested greater GFR recovery with avacopan as compared to glucocorticoid therapy. Practical treatment regimens for induction of remission include rituximab plus glucocorticoid or avacopan, cyclophosphamide plus glucocorticoid or avacopan, or rituximab and cyclophosphamide plus glucocorticoid. • Tavneos is indicated for severe active disease. According to the American College of Rheumatology/Vasculitis Foundation, active disease is defined as new, persistent, or worsening clinical signs and/or symptoms attributed to GPA, MPA, or EGPA and not related to prior damaged. Remission is the absence of clinical signs and symptoms. Severe disease is defined as vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia), and non-severe disease is lack of these manifestations. • Prescribing Considerations: ○ Tavneos is not recommended in patients with active, untreated and /or uncontrolled chronic liver disease and cirrhosis. ○ Tavneos has warnings and/or precautions for hepatotoxicity, serious hypersensitivity reactions (including angioedema), hepatitis B virus reactivation, and serious infections. ○ Tavneos does not have dose adjusting requirements for renally impaired patients. Dosing for patients on dialysis has not been studied. ○ Tavneos should not be used with strong CYP3A4 enzyme inducers ○ If Tavneos is used in combination with strong CYP3A4 inhibitors, the dose should be reduced to 30 mg once daily.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Tavneos may be approved when all of the following criteria are met **(A. through D.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of one (1) of the following **(1. or 2.)**:
- **1.** GPA (i.e., Wegener's Granulomatosis) (ICD-10: M31.3), classified as severe active disease.
- **2.** MPA (ICD-10: M31.7), classified as severe active disease.

C. The prescriber attests that the member has one (1) of the following **(1. or 2.)**:
- **1.** Positive test for anti-PR3
- **2.** Positive test for anti-MPO

D. The member will receive concomitant standard of care with immunosuppressants (e.g., rituximab, cyclophosphamide, azathioprine, mycophenolate mofetil) for the treatment of active severe GPA or MPA.

II. Reauthorization

When a benefit, reauthorization of Tavneos may be approved when all of the following criteria are met **(A. and B.)**:

A. The prescriber attests that the member demonstrates therapeutic response, defined as one (1) of the following **(1. or 2.)**:

1. Disease stability
2. Disease improvement

B. The member will continue to receive concomitant standard of care with immunosuppressants (e.g., rituximab, cyclophosphamide, azathioprine, mycophenolate mofetil) for the treatment of GPA or MPA.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Tavneos [package insert]. Cincinnati, OH: ChemoCentryx, Inc; June 2024.
2. Genetic and Rare Diseases Information Center. Anca-associated vasculitis. Available at: https://rarediseases.info.nih.gov/diseases/13011/anca-associated-vasculitis. Accessed October 14, 2024.
3. Rovin B, Floege J, et al. KDIGO Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int.* 2021;100(45): S1-S276.
4. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody–Associated Vasculitis. *Arthritis Care Res*. 2021; 73(8):1088-1105.
5. Rovin B, Floege J, et al. KDIGO 2024 Clinical Practice Guideline for the Management of Antineutrophil Cytoplasmic Antibody (ANCA)–Associated Vasculitis. *Kidney Int*. 2024; 105(3): s71-S116.