

<b>Effective date: 04/01/2022</b>
Reviewed: 01/2022, 3/2023, 2/2024, 2/2025, 3/2026
Scope: Medicaid

## TAVNEOS (avacopan)

### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indication

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.

All other indications are considered experimental/investigational and not covered benefits.

#### II. CRITERIA FOR INITIAL APPROVAL

##### **Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA])**

Authorization of 6 months may be granted for treatment of severe active ANCA-associated vasculitis (GPA and MPA) when all of the following are met:

- A. Documentation that Tavneos will be used in combination with standard therapy (e.g., cyclophosphamide, azathioprine, mycophenolate, rituximab)
- B. Documentation that the member is positive for anti-PR3 or anti-MPO antibody
- C. Documentation of pretreatment objective assessment of the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic)

#### III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment for severe active ANCA-associated vasculitis (GPA and MPA) in members with documentation who achieve or maintain positive clinical response as evidenced by stabilization or improvement in the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic).

#### IV. QUANTITY LIMIT

- Tavneos 10mg capsules: 6 capsules a day

<b>Effective date: 04/01/2022</b>
Reviewed: 01/2022, 3/2023, 2/2024, 2/2025, 3/2026
Scope: Medicaid

## V. REFERENCES

1. Tavneos [package insert]. Cincinnati, OH: ChemoCentryx, Inc.; June 2025. Accessed March 2026.
2. American College of Rheumatology. 2021 American college of rheumatology/vasculitis foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis & Rheumatology*. <https://www.vasculitisfoundation.org/wp-content/uploads/2021/07/2021-ACR-VF-Guideline-for-Management-of-ANCA-Associated-Vasculitis.pdf>. Accessed October 21, 2021.
3. Geetha D, Jefferson JA. ANCA-Associated vasculitis: Core curriculum 2020. *Am J Kidney Dis*. 75(1): 124-137.
4. Jayne DRW, Merkel PA, Schall TJ et al. Avacopan for the treatment of ANCA-associated vasculitis [supplemental appendix]. *N Engl J Med*. 2021; 384:599-609. DOI: 10.1056/NEJMoa2023386. [https://www.nejm.org/doi/suppl/10.1056/NEJMoa2023386/suppl\\_file/nejmoa2023386\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2023386/suppl_file/nejmoa2023386_appendix.pdf). Accessed October 28, 2021.