

Program Number	2025 P 2265-4
Program	Prior Authorization/Medical Necessity
Medication	Tavneos® (avacopan)
P&T Approval Date	1/2022, 1/2023, 1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Tavneos (avacopan) is a complement 5a receptor (C5aR) antagonist indicated as an 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.

2. Coverage Criteria ^a:

A. Anti-Neutrophil Cytoplasmic Autoantibody (ANCA) - Associated Vasculitis

1. Initial Authorization

a. Tavneos will be approved based on **all** of the following criteria:

(1) Diagnosis of severe active ANCA-associated vasculitis

-AND-

(2) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting the disease is **one** of the following types:

(a) Granulomatosis with polyangiitis (GPA)

(b) Microscopic polyangiitis (MPA)

-AND-

(3) Patient is being treated with an initial immunosuppressive regimen to induce remission (i.e., rituximab, cyclophosphamide)

-AND-

(4) Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g. prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

-AND-

(5) Prescribed by **one** of the following:

- (a) Rheumatologist
- (b) Nephrologist
- (c) Pulmonologist
- (d) Vascular Medicine Specialist

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Tavneos** will be approved based on **all** of the following criteria:

- (1) Patient does not show evidence of progressive disease while on Tavneos therapy

-AND-

- (2) Tavneos is being prescribed as adjunctive treatment in combination with standard therapy (e.g. prednisone, azathioprine, mycophenolate, methotrexate, rituximab, cyclophosphamide)

-AND-

- (3) Prescribed by or in consultation with **one** of the following:

- (a) Rheumatologist
- (b) Nephrologist
- (c) Pulmonologist
- (d) Vascular Medicine Specialist

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.



4. References:

1. Tavneos [package insert]. Cincinnati, OH: Thermo Fisher Scientific; June 2024.

Program	Prior Authorization/Medical Necessity - Tavneos [®] (avacopan)
Change Control	
1/2022	New program
1/2023	Annual review with no change to coverage criteria.
1/2024	Annual review with no changes.
1/2025	Annual review with no changes to coverage criteria. Updated reference.