UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2265-3
Program	Prior Authorization/Medical Necessity
Medication	Tavneos® (avacopan)
P&T Approval Date	1/2022, 1/2023, 1/2024
Effective Date	4/1/2024

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; October 2021.

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.