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5.85.043

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Hematological Agents	**Original Policy Date:**	October 29, 2021
Subject:	Tavneos	**Page:**	1 of 5

Last Review Date: March 7, 2025

Tavneos

Description

Tavneos (avacopan)

Background
Tavneos (avacopan) is a small molecule antagonist of complement 5a receptor (C5aR), which disrupts the receptors interaction with ligand C5a. Anaphylatoxin C5a is a proinflammatory component of the complement system which targets both immune and non-immune cells to mediate vasodilation, increase small blood vessel permeability, and induce smooth muscle contraction. Tavneos targets the C5aR and blocks the migration of neutrophils. The precise mechanism of how Tavneos exerts a therapeutic effect is not definitively established (1).

Regulatory Status
FDA-approved indication: Tavneos 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 (1).

In clinical trials with Tavneos, serious hypersensitivity reactions, hepatitis B virus reactivation, serious infections, and increases in liver function tests were reported. Patients should be monitored closely for signs and symptoms of angioedema and hepatitis B reactivation, and proper medical management instituted accordingly. Tavneos should not be used in patients with active serious infections, including localized infections. Additionally, liver function tests should be obtained before initiation of therapy and monitored as clinically indicated (1).

Tavneos exposure is decreased when co-administered with strong CYP3A4 enzyme inducers such as rifampin. Coadministration of strong and moderate CYP3A4 inducers with Tavneos should be avoided (1).

The safety and effectiveness of Tavneos in pediatric patients have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tavneos may be considered **medically necessary** if the conditions indicated below are met.

Tavneos may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis

AND ONE of the following
1. Granulomatosis with polyangiitis (GPA)
2. Microscopic polyangiitis (MPA)

AND ALL of the following:
1. Used in combination with standard therapy, including glucocorticoids
2. Absence of active infections (including tuberculosis and hepatitis B virus [HBV])

3. Patients with evidence of current or prior HBV infection **only**: prescriber agrees to monitor for HBV reactivation during therapy and for 6 months following Tavneos therapy
4. Liver function tests (LFTs) must be obtained prior to starting therapy
5. Prescriber agrees to monitor LFTs throughout therapy

Prior–Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis

AND ONE of the following
1. Granulomatosis with polyangiitis (GPA)
2. Microscopic polyangiitis (MPA)

AND ALL of the following:
1. Used in combination with standard therapy including glucocorticoids
2. Absence of active infections (including tuberculosis and hepatitis B virus (HBV)
3. Patients with evidence of current or prior HBV infection **only**: prescriber agrees to monitor for HBV reactivation during therapy and for 6 months following Tavneos therapy
4. Prescriber agrees to monitor LFTs throughout therapy

Policy Guidelines

Pre–PA Allowance

None

Prior–Approval Limits

Quantity

Drug	Quantity per 90 days

Tavneos 10mg	540 capsules

Duration 12 months

Prior–Approval *Renewal* Limits

Same as above

Rationale

Summary

Tavneos is an antagonist of the C5aR approved for the treatment of (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. By blocking the interaction between the receptor (C5aR) and its ligand (C5a), Tavneos inhibits the migration of neutrophils. Although not fully understood, it is thought that this is primary mechanism through which Tavneos exerts a therapeutic effect. In clinical studies, Tavneos was associated with an increase in liver function tests and serious infection. These adverse events should be monitored for and managed as medically appropriate. The safety and effectiveness of Tavneos in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tavneos while maintaining optimal therapeutic outcomes.

References

1. Tavneos [package insert]. Thousand Oaks, CA: ChemoCentryx, Inc.; June 2024.

Policy History

Date	Action
October 2021	Addition to PA
December 2021	Annual review
March 2022	Annual review. Per SME, added requirement “Patients with evidence of current or prior HBV infection only: prescriber agrees to monitor for HBV reactivation during therapy and for 6 months following Tavneos therapy”
December 2022	Annual review. Changed policy number to 5.85.043
December 2023	Annual review

March 2024	Annual review and reference update
September 2024	Annual review and reference update. Per SME, added statement regarding coadministration with CYP3A4 inducers to regulatory status section
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.