BlueCross BlueShield Federal Employee Program

# TAVNEOS
# (avacopan)

## RATIONALE FOR INCLUSION IN PA PROGRAM

### 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).

### 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.