

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Tavneos Clinical Edit
<b>First Implementation Date:</b>	TBD
<b>Proposed Date:</b>	March 17, 2022
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input checked="" type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of Tavneos™ (avacopan)

**Why Issue Selected:** On October 7, 2021 the FDA approved Tavneos™ (avacopan) as 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. ANCA-associated vasculitis (AAV) refers to a group of autoimmune disorders characterized by destruction and inflammation of small blood vessels, with approximately 75% of patients having kidney involvement. AAV has an incidence of 200 to 400 cases per million people, affecting an estimated 60,000 people in the United States. AAV is caused by ANCAs binding to neutrophils, causing them to attack small blood vessels in the body. Symptoms of AAV depend on which organs are affected, but may include the kidneys, heart, lungs, and skin. The goals of therapy include induction of remission, followed by maintenance of remission to prevent relapse.

Tavneos is the first FDA-approved oral complement C5a receptor (C5aR) inhibitor and represents the first drug approved for AAV in the past decade. Tavneos works by inhibiting the interaction between the C5aR and the C5a fragment of the complement cascade, resulting in decreased neutrophil activation and migration. It is intended to be used with standard therapy including glucocorticoids but does not eliminate glucocorticoid use.

Due to the high cost and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Tavneos.

Program-Specific Information:	Drug	Cost per capsule (MAC)	Cost per month (MAC)	Cost per year (MAC)
	TAVNEOS 10 MG CAPSULE	\$79.96	\$14,392.80	\$175,112.40

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Tavneos (avacopan)
- Age range: All appropriate MO HealthNet participants aged 18 years and older

## Approval Criteria

### Initial Therapy:

- Prescribed by or in consultation with a rheumatologist, nephrologist, or other specialist in the treated disease state **AND**
- Participant is aged 18 years or older **AND**
- Documented diagnosis of severe acute GPA or MPA types AAV **AND**
- Documentation of positive test for proteinase 3 (PR3)-ANCA or myeloperoxidase (MPO)-ANCA **AND**
- Documentation of baseline clinical criteria (e.g., liver function tests, estimated glomerular filtration rate, Vasculitis Damage Index) **AND**
- Participant is currently receiving or beginning standard therapy including glucocorticoids for induction of remission
- Initial approval for 6 months

### Continuation of Therapy:

- Continued approval for 12 months may be given following documentation of:
  - Clinical benefit of therapy (e.g., decreased glucocorticoid dose, improved or sustained renal function, improved BVAS score, sustained VDI score) **AND**
  - Demonstrated evidence of continued need in maintenance of remission while on standard therapy (e.g., rituximab, azathioprine, or methotrexate)

## Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant has history of severe hepatic impairment (Child Pugh C)
- Participant has history of kidney transplant
- Participant has history of Chronic Kidney Disease Stage 5 or End-Stage Renal Disease
- Participant is currently pregnant

## Required Documentation

Laboratory Results:

Progress Notes:

MedWatch Form:

Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)

Rule Type: CE

## Default Approval Period

6 months

*SmartPA Clinical Proposal Form*

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