

SmartPA Criteria Proposal

Drug/Drug Class:	Tavneos Clinical Edit
First Implementation Date:	TBD
Proposed Date:	March 17, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<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 GPA or MPA types AAV **AND**
- Documentation of positive test for proteinase 3 (PR3)-ANCA or myeloperoxidase (MPO)-ANCA **AND**
- Documentation of at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (BVAS) **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:

MedWatch Form:

Progress Notes:

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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