SmartPA Criteria Proposal

Drug/Drug Class:	Tavneos Clinical Edit
First Implementation Date:	August 4, 2022
Proposed Date:	April 18, 2023
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 (WAC)	Cost per month (WAC)	Cost per year (WAC)
TAVNEOS 10 MG CAPSULE	$85.00	$15,300	$183,600

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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 active 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:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

- Tavneos (avacopan) [package insert]. Cincinnati, OH: ChemoCentryx, Inc.; October 2021.
- UNC Kidney Center. ANCA Vasculitis. ANCA Vasculitis | UNC Kidney Center. Updated September 2018. Accessed January 24, 2023.
- Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases (kidney-international.org). Kidney Int. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021.
- Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Rheumatol. 2021;73(8):1366-1383. doi:10.1002/art.41773. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody–Associated Vasculitis - Chung - 2021 - Arthritis & Rheumatology - Wiley Online Library.
- Samman KN, Ross C, Pagnoux C, Makhzoum JP. Update in the Management of ANCA-Associated Vasculitis: Recent Developments and Future Perspectives. Int J Rheumatol. 2021;2021:5534851. Published 2021 Apr 8. doi:10.1155/2021/5534851. Update in the Management of ANCA-Associated Vasculitis: Recent Developments and Future Perspectives (nih.gov).
- Almaani S, Fussner LA, Brodsky S, Meara AS, Jayne D. ANCA-Associated Vasculitis: An Update. J Clin Med. 2021;10(7):1446. Published 2021 Apr 1. doi:10.3390/jcm10071446. ANCA-Associated Vasculitis: An Update (nih.gov).
- NIH: U.S National Library of Medicine. A Study to Evaluate the Safety and Efficacy of CCX168 in Subjects with ANCA-Associated Vasculitis. A Study to Evaluate the Safety and Efficacy of CCX168 in Subjects With ANCA-Associated Vasculitis - Full Text View - ClinicalTrials.gov. Accessed November 4, 2021.
- Jayne DRW, Bruchfeld AN, Harper L, et al. Randomized Trial of C5a Receptor Inhibitor Avacopan in ANCA-Associated Vasculitis. J Am Soc Nephrol. 2017;28(9):2756-2767. doi:10.1681/ASN.2016111179. Randomized Trial of C5a Receptor Inhibitor Avacopan in ANCA-Associated Vasculitis | American Society of Nephrology (asnjournals.org).
- NIH: U.S National Library of Medicine. Clinical Trial to Evaluate Safety and Efficacy of CCX168 in ANCA-Associated Vasculitis. Clinical Trial to Evaluate Safety and Efficacy of CCX168 in ANCA-Associated Vasculitis - Full Text View - ClinicalTrials.gov. Accessed November 4, 2021.
- Merkel PA, Niles J, Jimenez R, et al. Adjunctive Treatment with Avacopan, an Oral C5a Receptor Inhibitor, in Patients with Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. ACR Open Rheumatol. 2020;2(11):662-671. doi:10.1002/acr2.11185. Adjunctive Treatment With Avacopan, an Oral C5a Receptor Inhibitor, in Patients With Antineutrophil Cytoplasmic Antibody–Associated Vasculitis - Merkel - 2020 - ACR Open Rheumatology - Wiley Online Library.
- NIH: U.S National Library of Medicine. A Phase 3 Clinical Trial of CCX168 (Avacopan) in Patients with ANCA-Associated Vasculitis (ADVOCATE). A Phase 3 Clinical Trial of CCX168 (Avacopan) in Patients With ANCA-Associated Vasculitis - Full Text View - ClinicalTrials.gov. Accessed November 4, 2021.
- Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. N Engl J Med. 2021;384(7):599-609. doi:10.1056/NEJMoa2023386. Avacopan for the Treatment of ANCA-Associated Vasculitis | NEJM.
- Luqmani, RA, et al. Clinical Evaluations of Systemic Vasculitis: A Practical Guide to Using BVAS and VDI, Version 8.1. CLINICAL EVALUATION OF SYSTEMIC (tcd.ie) Updated July 27, 2018. Accessed November 8, 2021.