CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Tavneos (avacopan)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Tavneos, approved by the FDA in 2021, is indicated as an adjunctive treatment for severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. (It is NOT approved for eosinophilic granulomatosis with polyangiitis [EGPA]).
ANCA-associated vasculitis (AAV) is thought to be caused by an overactivation of the complement system, leading to excess generation of complement fragment 5a (C5a). C5a is a chemoattractant involved in recruiting inflammatory cells that can cause damage to blood vessels. Tavneos is an oral complement inhibitor that selectively blocks the C5a receptor (CD88). In the phase 3 ADVOCATE clinical trial, Tavneos was noninferior to prednisone taper for remission at 26 weeks, but superior for sustained remission at 52 weeks. Disease activity and remission are measured using the Birmingham Vasculitis Activity Score (BVAS).
AAV is a group of progressive autoimmune disease with circulating ANCA autoantibodies, inflammation, and damage to small and sometimes medium sized blood vessels. Multiple organ systems may be affected and most patients have renal involvement. Kidney biopsy is the gold standard for diagnosis but clinical presentation and serology are also used, especially in rapidly progressive cases.

Tavneos (avacopan) will be considered for coverage when the following criteria are met:

Antineutrophil Cytoplasmic Autoantibody (ANCA)- Associated Vasculitis

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist or rheumatologist; AND
3. Member has a diagnosis of severe active granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA); AND
4. Documentation of positive test for autoantibodies against myeloperoxidase (MPO) or proteinase 3 (PR3); AND
5. Member meets one of the following:
   a) Trial and failure of cyclophosphamide (IV or oral) + glucocorticoid
   b) Trial and failure of rituximab + glucocorticoid; AND
6. Tavneos will be used in combination with standard immunosuppressive therapy (e.g., rituximab or cyclophosphamide) AND glucocorticoids (unless contraindication is documented); AND
7. Member has at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the BVAS (see appendix); AND
8. Liver function tests (ALT, AST) have been or will be obtained before starting Tavneos; AND
9. Member does not have severe hepatic impairment (Child-Pugh C); AND
10. Member's eGFR is 15 mL/min or greater; AND
11. Member is not currently on dialysis and has not had a kidney transplant.
12. **Dosage allowed/Quantity limit:** 30 mg (three 10 mg capsules) twice daily. (180 capsules per 30 days)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show improvement or stabilized signs and symptoms of disease such as decreased BVAS, improved or sustained renal function, or ability to decrease or discontinue corticosteroids.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Tavneos (avacopan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
02/04/2022	New policy for Tavneos created.

APPENDIX: Birmingham Vasculitis Activity Score (BVAS)
The BVAS organ systems are shown below. ***Major items are indicated in bold italics***. The score is on a scale from 0 to 63, with higher scores indicating greater disease activity. A score of 0 indicates remission.

Body Systems:

1. General
• Myalgia
• Arthralgia / arthritis
• Fever ≥38 °C
• Weight loss ≥2 kg

2. Cutaneous
• Infarct
• Purpura
• Ulcer
• ***Gangrene***
• Other skin vasculitis

3. Mucous membranes / eyes
• Mouth ulcers
• Genital ulcers
• Adnexal inflammation
• Significant proptosis
• ***Scleritis / Episcleritis***
• Conjunctivitis / Blepharitis / Keratitis
• Blurred vision
• Sudden visual loss
• Uveitis
• ***Retinal changes (vasculitis / thrombosis / exudate / haemorrhage)***

4. Ear Nose & Throat
• Bloody nasal discharge / crusts / ulcers / granulomata
• Paranasal sinus involvement
• Subglottic stenosis
• Conductive hearing loss
• ***Sensorineural hearing loss***

5. Chest
• Wheeze
• Nodules or cavities
• Pleural effusion / pleurisy
• Infiltrate
• Endobronchial involvement
• ***Massive hemoptysis / alveolar hemorrhage***
• ***Respiratory failure***

6. Cardiovascular
• Loss of pulses
• Valvular heart disease
• Pericarditis
• Ischemic cardiac pain
• Cardiomyopathy
• Congestive cardiac failure

7. Abdominal
• Peritonitis
• Bloody diarrhea
• ***Ischemic abdominal pain***

8. Renal
• Hypertension
• Proteinuria >1+ or >0.2 g/g creatinine
• Hematuria ≥10 RBCs/hpf
• Serum creatinine 125-249 µmol/L

• Serum creatinine 250-499 µmol/L
• Serum creatinine ≥500 µmol/L
• Rise in serum creatinine >30% or fall in creatinine clearance >25%

9. Nervous system
• Headache
• Meningitis
• Seizures (not hypertensive)
• Cerebrovascular accident
• Organic confusion
• Spinal cord lesion
• Cranial nerve palsy
• Sensory peripheral neuropathy
• Mononeuritis multiplex

10. Other
• RBC casts and/or glomerulonephritis

References:

1. Tavneos [prescribing information]. ChemoCentryx, Inc.; 2021.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021
3. Merkel PA, Jayne DR, Wang C, Hillson J, Bekker P. Evaluation of the Safety and Efficacy of Avacopan, a C5a Receptor Inhibitor, in Patients With Antineutrophil Cytoplasmic Antibody-Associated Vasculitis Treated Concomitantly With Rituximab or Cyclophosphamide/Azathioprine: Protocol for a Randomized, Double-Blind, Active-Controlled, Phase 3 Trial. *JMIR Res Protoc*. 2020;9(4):e16664. Published 2020 Apr 7. doi:10.2196/16664
4. 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
5. 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
6. Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis [published correction appears in Ann Rheum Dis. 2017 Aug;76(8):1480]. Ann Rheum Dis. 2016;75(9):1583-1594. doi:10.1136/annrheumdis-2016-209133
7. 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 Care Res (Hoboken)*. 2021;73(8):1088-1105. doi:10.1002/acr.24634
8. IPD Analytics; accessed February 4, 2022.

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