PHARMACY POLICY STATEMENT
North Carolina 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
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