



Pharmacy Drug Policy & Procedure

Policy Name:	Tavneos (avacopan)	Policy#:	3256P
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Purpose of the Policy

The purpose of this policy is to define coverage criteria for Tavneos (avacopan)

Statement of the Policy

Health Alliance Medical Plans will approve the use of Tavneos (avacopan) under the specialty pharmacy benefit if the following criteria are met.

Criteria

1. Coverage Criteria

- 1.1 Diagnosis of one of the following types of severe active Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-associated vasculitis:
 - Granulomatosis with polyangiitis (Wegener’s granulomatosis)
 - Microscopic polyangiitis
- 1.2 Diagnosis confirmed by one of the following:
 - ANCA test positive for proteinase 3 (PR3) antigen
 - ANCA test positive for myeloperoxidase (MPO) antigen
 - Tissue biopsy
- 1.3 Documentation to support Birmingham Vasculitis Activity Score (BVAS) containing at least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria
- 1.4 Age 18 years or older
- 1.5 Prescribed by or in consultation with a rheumatologist (musculoskeletal doctor), nephrologist (kidney doctor), or immunologist (immune system doctor)
- 1.6 Patient is currently receiving standard therapy with cyclophosphamide or rituximab
- 1.7 Patient is currently on glucocorticoids or has a contraindication or intolerance

2. Exclusion Criteria

- 2.1 Currently on dialysis or previous kidney transplant
- 2.2 Diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA)

3. Managed Dose Limit

- 3.1 Maximum 180 capsules per 30 days

4. Approval Period

- 4.1 Initial: 12 months
- 4.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes

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HCPCS Codes

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References

1. Tavneos (avacopan) [prescribing information]. Cincinnati, OH: Thermo Fisher Scientific; October 2021.
2. 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.
3. Hellmich B, Sanchez-Alamo B, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis.* 2024 Jan 2;83(1):30-47.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.