

<b>Clinical Policy Title:</b>	avacopan
<b>Policy Number:</b>	RxA.765
<b>Drug(s) Applied:</b>	Tavneos®
<b>Original Policy Date:</b>	07/18/2022
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. ANCA-Associated Vasculitis (must meet all):

1. Diagnosis of granulomatosis with polyangiitis or microscopic polyangiitis variant of active neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis;
2. Must meet one of the following (a, b or c):
  - a. Positive test for anti-proteinase-3;
  - b. Positive test for anti-myeloperoxidase;
  - c. Positive indirect immunofluorescence test for P-ANCA or C-ANCA.
3. Member is currently receiving standard therapy with cyclophosphamide or rituximab.

#### Approval Duration

**All Lines of Business (except Medicare):** 6 months

### II. Continued Therapy Approval

#### A. ANCA-Associated Vasculitis (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

## References

1. Arthritis Advisory Committee Meeting FDA Briefing Document: NDA#214487. Available at: <https://www.fda.gov/media/148176/download>. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/02/2022	07/18/2022
Policy was Reviewed: 1. Initial Approval Criteria, I.A.4.c: Updated to include new diagnostic criteria Positive indirect immunofluorescence test for P-ANCA or C-ANCA. 2. Initial Approval Criteria, I.A:	06/29/2023	07/13/2023

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Removed “Documentation of baseline Birmingham vasculitis activity score (BVAS) with at least one of the following (a, b, or c): a. At least 1 major item; b. At least 3 non-major items. At least the 2 renal items of proteinuria and hematuria.”</p> <p>3. Initial Approval Criteria, I.A: Removed “Member has eGFR ≥ 15 mL/min/1.72 m<sup>2</sup>”, “Member does not currently require dialysis or have a kidney transplant, and has not received plasma exchange in the past 12 weeks”.</p> <p>4. References were reviewed and updated.</p>		
<p>Policy was reviewed.</p>	<p>10/19/2023</p>	<p>10/19/2023</p>
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. References were reviewed and updated.</li> </ol>	<p>8/28/2024</p>	<p>9/13/2024</p>
<p>Policy was reviewed.</p>	<p>12/05/2025</p>	<p>N/A</p>
<p>Policy reviewed.</p>	<p>12/11/2025</p>	<p>12/11/2025</p>