Clinical Policy Title:	avacopan
Policy Number:	RxA.765
Drug(s) Applied:	Tavneos®
Original Policy Date:	07/18/2022
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	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

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." 3. Initial Approval Criteria, I.A: Removed "Member has eGFR ≥ 15 mL/min/1.72 m^2 ", "Member does not currently require dialysis or have a kidney transplant, and has not received plasma exchange in the past 12 weeks". 4. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024