

Clinical Policy: Avacopan (Tavneos)

Reference Number: PA.CP.PHAR.515

Effective Date: 01/2022

Last Review Date: 01/2025

Description

Avacopan (Tavneos) is a complement 5 α receptor (c5 α R) antagonist.

FDA Approved Indication(s)

Tavneos is indicated as an adjunctive treatment of adult patients with severe active neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. Tavneos does not eliminate glucocorticoid use.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Tavneos is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of severe active ANCA-associated vasculitis that is one of the following types (a or b; *see Appendix D*):
 - a. GPA (formerly known as Wegener's);
 - b. MPA;
2. Prescribed by or in consultation with a rheumatologist, nephrologist, immunologist, or pulmonologist;
3. Age \geq 18 years;
4. One of the following (a, b, or c):
 - a. Positive indirect immunofluorescence test for P-ANCA or C-ANCA;
 - b. Positive ELISA test for anti-proteinase-3;
 - c. Positive ELISA test for anti-myeloperoxidase;
5. Tavneos is prescribed in combination with at least one of the following standard therapies, unless clinically significant adverse effects are experienced or all are contraindicated rituximab, cyclophosphamide, azathioprine or mycophenolate mofetil (if member is unable to use azathioprine);*
 - a. Rituximab or cyclophosphamide;
 - b. Azathioprine or mycophenolate mofetil (if member is unable to use azathioprine);

**Prior authorization may be required*
6. Dose does not exceed 60 mg (6 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies iteria;
2. Member is responding positively to therapy as evidenced by by an improvement in at least one objective disease measure from baseline, not limited to (a, b or c):
 - a. Increase in estimated glomerular filtration rate;
 - b. Decrease in urinary albumin creatinine ratio;
 - c. Improvement in the Birmingham Vasculitis Activity Score [BVAS]);
3. If request is for a dose increase, new dose does not exceed 60 mg (6 capsules) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ANCA: antineutrophil cytoplasmic antibody
BVAS: Birmingham vasculitis activity score
c5aR: complement 5a receptor
ELISA: enzyme-linked immunosorbent assay

GPA: granulomatosis with polyangiitis
FDA: Food and Drug Administration
MPA: microscopic polyangiitis

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Serious hypersensitivity to avacopan or to any of the excipients
- Boxed warning(s): None

Appendix D: General Information

- Severe disease associated with GPA and MPA is defined as vasculitis with life-or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia).

- Active disease associated with GPA and MPA is defined as new, persistent, or worsening clinical signs and/or symptoms attributed to GPA or MPA and not related to prior damage.
- *Birmingham Vasculitis Activity Score (BVAS)*
 - BVAS is a composite score made up of 59 items organized into 9 different groups, expressing possible organ involvement: general, cutaneous, mucous/membranes/eyes, ear/nose/throat, chest, cardiovascular, abdominal, renal, nervous system, and other
 - The maximum scores vary for each section, and differ based on whether the symptoms are classified as new/worse or persistent. The higher the global score achieved, the more severe the disease; the maximum attainable scores are 33 and 63 for BVAS persistent and BVAS new/worse respectively.
 - Major items include the following:
 - Cutaneous: gangrene
 - Mucous/membrane/eyes: scleritis, retinal exudates/hemorrhage
 - Ear/nose/throat: sensorineural deafness
 - Abdominal: mesenteric ischemia
 - Pulmonary: alveolar hemorrhage, respiratory failure
 - Renal: RBC casts, rise in creatinine > 30% or fall in creatinine > 25%
 - Nervous system: meningitis, cord lesion, stroke, cranial nerve palsy, sensory peripheral neuropathy, motor mononeuritis multiplex

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ANCA-associated vasculitis	30 mg PO BID	60 mg/day

VI. Product Availability

Oral capsule: 10 mg

VII. References

1. Tavneos Prescribing Information. Cincinnati, OH: ChemoCentryx, Inc: June 2024. Available at <https://tavneos.com/>. Accessed November 25, 2024.
2. Jayne D, Bruchfeld A, Harper L, et al. Randomized trial of C5a receptor inhibitor avacopan in ANCA-associated vasculitis. *J Am Soc Nephrol*. 2017; 28: 2756-2767. doi: 10.1681/ASN.2016111179.
3. Merkel PA, Jayne DR, Wang C, Hillson J, and 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 doi: 10.2196/16664:10.2196/16664.
4. Walsh M, Merkel PA, Mahr A, and Jayne D. The effects of duration of glucocorticoid therapy on relapse rate in anti-neutrophil cytoplasm antibody associated vasculitis: a meta-analysis. *Arthritis Care Res*. 2010; 62(8): 1166-1173. doi: 10.1002/acr.20176.
5. 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 Rheumatol*. 2021;73(8):1366-1383. doi:10.1002/art.41773

6. Jayne D, Merkel P, Schall T, et al. Avacopan for the Treatment of ANCA-Associated Vasculitis. *N Engl J Med.* 2021 Feb 18; 384(7): 599-609.
7. Arthritis Advisory Committee Meeting FDA Briefing Document: NDA#214487. Available at: <https://www.fda.gov/media/148176/download>. Accessed October 26, 2022.
8. Hellmich B, Sanchez-Alamo B, Schirmer JH, et al. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis.* 2024;83(1):30-47.

Reviews, Revisions, and Approvals	Date
Policy created	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: clarified that concomitant standard therapy include at least one of the listed drugs per pivotal trial study and competitor criteria; references reviewed and updated.	01/2024
1Q 2025 annual review: added nephrologist, immunologist, and pulmonologist to specialists; removed criterion for documentation of baseline BVAS and added requirement for a diagnosis of severe active ANCA-associated vasculitis per competitor analysis; revised positive response criteria from BVAS of 0 and no glucocorticoid use to improvement in at least one objective measure from baseline; references reviewed and updated.	01/2025