Clinical Policy: Avacopan (Tavneos)

Reference Number: PA.CP.PHAR.515
Effective Date: 01/2022
Last Review Date: 01/2024

Coding Implications
Revision Log

Description
Avacopan (Tavneos) is a complement 5α receptor (c5αR) 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 polyangitis [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 granulomatosis with polyangiitis (formerly known as Wegener's) or microscopic polyangiitis;
2. Prescribed by or in consultation with a rheumatologist;
3. Age ≥ 18 years;
4. Must meet 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. Documentation of baseline Birmingham vasculitis activity score (BVAS, *see Appendix D)*, with at least one of the following (a, b, or c):
   a. At least 1 major item;
   b. At least 3 non-major items;
   c. At least the 2 renal items of proteinuria and hematuria;
6. 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*
7. 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.LTSS.PHAR.01) applies iteria;
2. Member is responding positively to therapy as evidenced by both of the following (a and b):
   a. Disease remission (BVAS of zero);
   b. No use of glucocorticoids;
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
c5αR: complement 5α 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: 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: October 2021. Available at https://tavneos.com/. Accessed October 12, 2023.
2. Jayne D, Bruchfeld A, Harper L, et al. Randomized trial of C5a receptor inhibitor avacopan in ANCA-asscoiated 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.
Arthritis Advisory Committee Meeting FDA Briefing Document: NDA#214487. Available at: https://www.fda.gov/media/148176/download. Accessed October 26, 2022.

Reviews, Revisions, and Approvals	Date
Policy created	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023

Reviews, Revisions, and Approvals	Date
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