Clinical Policy: Avacopan (Tavneos)

Reference Number: CP.PHAR.515
Effective Date: 10.07.21
Last Review Date: 02.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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 ≥ 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, 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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. ANCA-Associated Vasculitis (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
2. Member is responding positively to therapy as evidenced by an improvement in at least one objective disease measure from baseline (e.g., increase in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, 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 (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 reported

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, sensoryperipheral 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-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.
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	P&T Approval Date
Policy created pre-emptively; references to HIM.PHAR.21 revised to HIM.PA.154.	12.01.20	02.21
1Q 2022 annual review: RT4: policy updated per FDA approval; revised required combination therapy to include azathioprine or mycophenolate; revised criteria for continued authorizations to	10.26.21	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
require disease remission to align with primary outcome of pivotal clinical trial; clarified capsule proposed formulation per prescribing information; references reviewed and updated.		
Template changes applied to other diagnoses/indications.	10.03.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	10.27.22	02.23
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.	11.01.23	02.24
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.	11.25.24	02.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or

regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.