Clinical Policy: Avacopan (Tavneos)

Reference Number: ERX.SPA.422
Effective Date: 10.07.21
Last Review Date: 02.22
Line of Business: Commercial, 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 (Wegener's) or microscopic polyangiitis;
2. Prescribed by or in consultation with a rheumatologist;
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 enzyme-linked immunosorbent assay (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 both of the following standard therapy, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):*
   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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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 (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 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

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: red blood cell 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 26, 2021
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 September 16, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	12.01.20	02.21
1Q 2022 annual review: RT4: drug is now FDA approved - criteria updated per FDA labeling; revised required combination therapy to include azathioprine or mycophenolate; revised criteria for continued authorizations to require disease remission to align with primary outcome of pivotal clinical trial; clarified capsule formulation per prescribing information; references reviewed and updated.	10.26.21	02.22

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

be bound by the foregoing terms and conditions, in addition to the Site Use Agreement for Health Plans associated with Envolve Pharmacy Solutions.