MEDICAL MUTUAL®

Drug Policy

Policy:	Tavneos (avacopan)	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

Tavneos is a complement 5a receptor (C5aR) antagonist indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids.

POLICY STATEMENT

This policy involves the use of Tavneos. Prior authorization is recommended for pharmacy benefit coverage of Tavneos. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tavneos as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tavneos be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tavneos is recommended in those who meet the following criteria:

1. <u>Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, initial therapy</u>
Criteria. *Patient must meet the following criteria*

- **A.** The patient is 18 years of age or older; AND
- **B.** The patient has granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) [NOTE: granulomatosis with polyangiitis (GPA) is also known as Wegener's granulomatosis]; AND
- **C.** Patient has severe active disease [NOTE: this includes patients that have newly diagnosed or relapsed disease, but does NOT include patients already in remission]; AND
- **D.** Patient is positive for proteinase 3, myeloperoxidase antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA)* ; AND
- **E.** Patient is using this medication in combination with at least one immunosuppressant [NOTE: examples of immunosuppressants include cyclophosphamide, rituximab, azathioprine, or mycophenolate mofetil]; AND

F. The medication is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist; AND
G. The patient meets one of the following*:
  a. The patient has been assessed at baseline (prior to initiating Tavneos) by at least one objective measure, including estimated glomerular filtration rate (eGFR), urinary albumin creatinine ratio, or Birmingham Vasculitis Activity Score (BVAS); OR
  b. At baseline (prior to initiating Tavneos), the patient has at least one of the following symptoms: joint pain, ulcers, myalgia, persistent cough, abdominal pain, or serious impairment in function or activities of daily living.

2. <u>Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis, continuation of therapy</u>
Criteria. *Patient must meet the following criteria*

A. The patient is 18 years of age or older; AND
B. The patient has been established on Tavneos for at least 6 months; AND
C. The medication is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist; AND
D. The patient will continue to use Tavneos in combination with standard therapy including glucocorticoids; AND
E. The patient meets at least one of the following*:
  a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos) [NOTE: examples of objective measures include improvement in estimated glomerular filtration rate (eGFR), decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score (BVAS)]; OR
  b. Compared with baseline (prior to initiating Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, or abdominal pain, or improvement in function or activities of daily living.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

***Documentation Required:** When <u>documentation</u> is required, the prescriber must provide written documentation supporting the evidence requested. Documentation should include chart notes, prescription claims records, and/or prescription receipts and/or lab values.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tavneos has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Eosinophilic Granulomatosis with Polyangiitis (EGPA).** There are no data evaluating Tavneos for EGPA. Patients with this condition were excluded from the pivotal study. Note: EGPA is also known as Churg-Strauss syndrome.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tavneos [prescribing information]. Cincinnati, OH: ChemoCentryx; October 2021.
2. Chung S, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guidelines for the management of antineutrophil cytoplasmic antibody-associated vasculitis. Arthritis Care and Research. 2021; 73(8):1088-1105.
3. Jayne DRW, Merkel PA, Schall TJ, et al. Avacopan for the treatment of ANCA-associated vasculitis. *N Engl J Med*. 2021;384(7):599-609.
4. Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. *Ann Rheum Dis*. 2016; 75(9):1583-1594.
5. Avacopan. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 18 April 2022. Accessed on 20 December 2022.