PRIOR AUTHORIZATION POLICY

POLICY: Vasculitis – Tavneos Prior Authorization Policy
- Tavneos® (avacopan capsules – ChemoCentryx)

REVIEW DATE: 07/10/2024

OVERVIEW

Tavneos, a complement 5a receptor antagonist, is indicated as an adjunctive treatment for **severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis** (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids in adults.[1] Tavneos does not eliminate glucocorticoid use.[1]

Disease Overview

ANCA-associated vasculitis is a group of diseases, which includes GPA (Wegener's granulomatosis), MPA, and eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome).[2] Patients who have ANCA-associated vasculitis produce antibodies that cause inflammation, which damages small blood vessels. The clinical signs and symptoms vary and affect several organs, such as the kidneys, lungs, stomach, and intestine. Many patients are positive for proteinase 3 or myeloperoxidase antibodies.[2] Patients normally undergo two phases of treatment; one designed to induce the remission of symptoms (induction treatment), and a second phase meant to keep patients in remission for as long as possible (maintenance treatment).[2] Response is measured by achieving remission or improvement of signs and symptoms, which can be assessed by improvement in the Birmingham Vasculitis Activity Score. Other indicators of clinical response include improvement in kidney function (i.e. improvement in estimated glomerular filtration rate), or decrease in urinary albumin creatinine ratio.[3]

Clinical Efficacy

The efficacy of Tavneos was evaluated in one Phase III, randomized, double-blind, active-controlled pivotal study that assessed the efficacy of Tavneos in patients with newly diagnosed or relapsing active ANCA-associated vasculitis.[3] Patients were randomized in a 1:1 ratio to receive Tavneos twice daily orally plus prednisone-matching placebo or a tapering oral regimen of prednisone plus Tavneos-matching placebo in a double-dummy design. Patients in both groups also received an immunosuppressive regimen (cyclophosphamide followed by azathioprine or mycophenolate mofetil; or rituximab). Patients included were positive for either proteinase 3 or myeloperoxidase antibodies.[3] Glucocorticoid use was allowed in each treatment group, if needed for certain situations.[3] The primary endpoints were remission at Week 26 and sustained remission at Week 52.[3] This pivotal trial demonstrated that Tavneos was noninferior but not superior to the prednisone taper with respect to remission at Week 26 and was superior to prednisone taper with respect to sustained remission at Week 52.[3]

Guidelines

The American College of Rheumatology/Vasculitis Foundation guidelines (2021) for the management of ANCA-associated vasculitis mention that a clinical trial of Tavneos in patients with GPA and MPA was published.[2] Treatment for ANCA-associated vasculitis is based on the severity of the disease, the disease status, and type. The following are recommendations from the guidelines for active, severe GPA/MPA. For remission induction, the guidelines recommend rituximab with reduced-dose glucocorticoids; cyclophosphamide may be used in certain clinical scenarios (i.e., contraindication or failure with rituximab).[2] If remission is not induced, the guidelines recommend switching to a different remission induction agent. For disease relapse, rituximab is recommended if the patient is not receiving rituximab

for remission maintenance; if the patient is taking rituximab for disease maintenance, the guidelines recommend switching from rituximab to cyclophosphamide.[2]

The European League against Rheumatism (EULAR)/European Renal Association – European Dialysis and Transport Association (2022) also have guidelines for ANCA-associated vasculitis.[4] The guidelines state that Tavneos, in combination with rituximab or cyclosporine may be considered for induction of remission in GPA or MPA as part of a strategy to substantially reduce exposure to glucocorticoids. Tavneos should be stopped after a duration of treatment of 6-12 months as there is no data on the use of Tavneos beyond 1 year, so longer-term use cannot be recommended.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tavneos. All approvals are provided for the duration noted below. 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 to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has granulomatosis with polyangiitis or microscopic polyangiitis; AND
       Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis.
     - **iii.** Patient has active disease; AND
       Note: This includes patients that have newly diagnosed or relapsed disease. This does not include patients already in remission.
     - **iv.** Patient is positive for proteinase 3 antibodies, myeloperoxidase antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA); AND
     - **v.** Patient is using this medication in combination with at least one immunosuppressant; AND
       Note: Examples of immunosuppressants include rituximab, methotrexate, azathioprine, and mycophenolate mofetil.
     - **vi.** The medication is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist.
   - **B)** Patient is Currently Receiving Tavneos. Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** Patient has been established on Tavneos for at least 6 months; AND
     - **iii.** Patient meets at least ONE of the following (a or b):
       - **a)** When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos); OR

Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS].

b) Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, skin rash, abdominal pain, or improvement in function or activities of daily living.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tavneos is not recommended in the following situations:

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.

REFERENCES

1. Tavneos™ capsules [prescribing information]. Cincinnati, OH: ChemoCentryx; June 2024.
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. Hellmich B, Sanchez-Alamo B, Schirmer JH. EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update. *Ann Rheum Dis*. 2024; 83(1):30-47.