Drug Coverage Policy

Effective Date..... 11/01/2024
Coverage Policy Number IP0398
Policy Title..... Tavneos

Vasculitis - Tavneos

- Tavneos™ (avacopan capsules - ChemoCentryx)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

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.

Medical Necessity Criteria

Tavneos is considered medically necessary when the following criteria are met:

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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	No clinical content change	6/15/2024
Annual Review	No criteria changes.	11/1/2024

The policy effective date is in force until updated or retired.