Effective Date **6/15/2023**
Next Review Date… **6/15/2024**
Coverage Policy Number **IP0398**

Avacopan

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Related Coverage Resources

Quantity Limitations - (1201)

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. 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.

Overview

This policy supports medical necessity review for avacopan capsules (**Tavneos**™).

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

Medical Necessity Criteria

Avacopan (Tavneos) is considered medically necessary when the following are met:

Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis. Individual meets **ALL** of the following criteria:

A. Age 18 years or older
B. Has granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)
C. Documentation of active disease

D. Has severe disease (for example, vasculitis with life- or organ-threatening manifestations [for example, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia])
E. Documentation of a positive test for proteinase 3 antibodies, myeloperoxidase antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA)
F. Avacopan (Tavneos) will be used as adjunctive therapy in combination with at least one standard immunosuppressant used for treatment of severe anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (for example, rituximab, methotrexate, azathioprine, mycophenolate mofetil, or cyclophosphamide)
G. Medication is prescribed by, or in consultation with, a rheumatologist or nephrologist

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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.

Reauthorization Criteria

Continuation of avacopan (Tavneos) is considered medically necessary for anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis when the individual meets **BOTH** of the following:

1. The above medical necessity criteria have been met prior to the start of Tavneos therapy
2. **ONE** of the following:
   A. When assessed by at least one objective measure, individual experienced a beneficial clinical response from baseline, prior to initiating Tavneos (for example, 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), individual 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

Authorization Duration

Initial approval duration: up to 6 months.
Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

Background

OVERVIEW
Tavneos, a complement 5a receptor antagonist, is indicated as an adjunctive treatment for adults 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.[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 kidney, 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 (2016) also have guidelines for ANCA-associated vasculitis. The guidelines recommend cyclophosphamide or rituximab with glucocorticoids for organ or life-threatening disease.[3] For patients with ANCA-associated vasculitis that is refractory to remission-induction therapy, the guidelines recommend switching from cyclophosphamide to rituximab or from rituximab to cyclophosphamide.[3]

References

1. Tavneos™ capsules [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.