avacopan (Tavneos™)

Policy # 00772
Original Effective Date: 03/14/2022
Current Effective Date: 03/10/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of avacopan (Tavneos™)‡ for the treatment of anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis to be **eligible for coverage.****

Patient Selection Criteria
Coverage eligibility for avacopan (Tavneos) will be considered when the following criteria are met:

- Initial Therapy
  - Patient has a diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA); AND
  - Patient is ≥18 years of age; AND
  - Patient is positive for proteinase 3 (PR3) or myeloperoxidase (MPO) antibodies; AND
  - Patient has active disease (i.e., patient is NOT currently in remission); AND
  - Patient does not currently require dialysis or have a kidney transplant and has not received plasma exchange in the past 12 weeks; AND
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
  - Patient is currently receiving standard therapy with cyclophosphamide or rituximab.
    *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Continuation Therapy
  - Patient has received an initial authorization for Tavneos; AND
  - Patient has experienced improvement while on therapy with Tavneos as evidenced by ONE of the following:
    - Documented improvement in at least one objective measure of clinical response compared to baseline. Examples of objective measures include improvement in estimated glomerular filtration rate, decrease in urinary albumin to creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score (BVAS); OR
    - Documentation of significant improvement compared to baseline 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.

  *(Note: These specific patient criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of avacopan (Tavneos) in patients who require dialysis, have a kidney transplant, or have received plasma exchange in the last 12 weeks or who are not currently receiving standard therapy with cyclophosphamide or rituximab to be **not medically necessary.****

Based on review of available data, the Company considers the continued use of avacopan (Tavneos) when the patient has not demonstrated improvement in objective measures or symptoms of GPA or MPA to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of avacopan (Tavneos) when the patient selection criteria are not met (except those noted to be **not medically necessary****) to be **investigational.***

Background/Overview

Tavneos is a complement 5a receptor antagonist that is indicated as an adjunctive treatment for adults with severe active granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA) in combination with standard therapy including glucocorticoids. It is available as a 10 mg capsule and should be dosed orally as 30 mg (three capsules) twice daily with food. Although Tavneos may reduce the glucocorticoid dose used in managing the condition, it does not eliminate glucocorticoid

use and is indicated for use in combination with glucocorticoids. Additionally, participants in the pivotal trial received a standard immunosuppressive regimen consisting of either cyclophosphamide followed by azathioprine or mycophenolate mofetil, or rituximab.

ANCA-associated vasculitis is a group of diseases which includes granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), and eosinophilic granulomatosis with polyangiitis. Diagnosis of these conditions includes testing for PR3 or MPO antibodies which are subtypes of ANCA. Each of these conditions causes damage to small blood vessels with varying clinical signs and symptoms. Almost any part of the body may be affected, however, the most commonly affected systems are the upper airways, lungs, kidneys, eyes, and peripheral nerves. If left untreated, the condition has a poor prognosis with increased morbidity and mortality. Current treatments have dramatically improved the management of ANCA-associated vasculitis but are associated with significant toxicity. Patients normally undergo two phases of treatment; one designed to induce the remission of symptoms (induction treatment), and a second phase to keep patients in remission (maintenance treatment). Standard therapies for induction treatment include rituximab and a reduced-dose glucocorticoid regimen or cyclophosphamide (intravenous or oral). Options for maintenance treatment include rituximab, azathioprine, and methotrexate. The choice of treatment depends on the severity of disease as well as the patient's age and prior treatments used.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Tavneos was approved in October 2021 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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy and safety of Tavneos was evaluated in a double-blind, active-controlled, phase 3 clinical trial in 330 patients with newly diagnosed or relapsed ANCA-associated vasculitis who had anti-PR3 or anti-MPO antibodies. Patients were randomized 1:1 to one of the following treatment groups:

1. Tavneos group (n=166): Patients received 30 mg Tavneos twice daily for 52 weeks plus prednisone-matching placebo for 20 weeks
2. Prednisone group (n=164): Patients received Tavneos-matched placebo twice daily for 52 weeks plus prednisone (tapered from 60 mg/day to 0 over 20 weeks).

All patients in both groups received a standard immunosuppressive regimen with either IV cyclophosphamide, oral cyclophosphamide, or IV rituximab. Glucocorticoids were allowed as pre-medication for rituximab to reduce hypersensitivity reactions, taper after glucocorticoids given during the screening period, treatment of persistent vasculitis, worsening of vasculitis, or relapses, as well as for non-vasculitis reasons such as adrenal insufficiency.

The primary endpoints of the study were disease remission at Week 26 and sustained disease remission at Week 52. Disease remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 22 to Week 26. Sustained remission was defined as remission at Week 26 and remission at Week 52, without relapse between Week 26 and Week 52. Remission at Week 52 was defined as BVAS of 0 and no use of glucocorticoids for treatment of ANCA-associated vasculitis from Week 48 to Week 52. Relapse was defined as occurrence of one major item, at least 3 non-major items, or 1 or 2 non-major items for at least 2 consecutive visits on the BVAS after remission (BVAS of 0) had been achieved.

Remission was achieved by 72.3% of patients in the Tavneos group and 70.1% of patients in the prednisone group at Week 26 (treatment difference: 3.4%, 95% CI -6.0%, 12.8%). At Week 52, a significantly higher percentage of patients had sustained remission in the Tavneos group (65.7%) compared to the prednisone group (54.9%) with a p=0.013.

References

1. Tavneos [package insert]. ChemoCentryx, Inc. Cincinnati, OH. Updated October, 2021.
2. Tavneos Drug Evaluation. Express Scripts. Updated October, 2021.
3. Granulomatosis with polyangiitis and microscopic polyangiitis: clinical manifestations and diagnosis. UpToDate. Updated January 2022.

Policy History

Original Effective Date: 03/14/2022
Current Effective Date: 03/10/2025

02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. New policy.
02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

avacopan (Tavneos™)

Policy # 00772
Original Effective Date: 03/14/2022
Current Effective Date: 03/10/2025

02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

avacopan (Tavneos™)

Policy # 00772
Original Effective Date: 03/14/2022
Current Effective Date: 03/10/2025

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.