Pharmacy Policy Bulletin

Title: Avacopan (Tavneos™)

Policy #: Rx.01.259

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Avacopan (Tavneos™)** as provided under the member's prescription drug benefit.

Description:

The antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis include granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), and eosinophilic granulomatosis with polyangiitis (EGPA). These vasculitis are complex, immune-mediated disorders in which tissue injury results from the interplay of an initiating inflammatory event and a highly specific immune response. Part of this response is directed against previously shielded epitopes of neutrophil granule proteins, leading to high-titer autoantibodies known as ANCA. The production of ANCA is one of the hallmarks of the ANCA-associated vasculitis. ANCA are directed against antigens present primarily within the granules of neutrophils and monocytes; these autoantibodies produce tissue damage via interactions with primed neutrophils and endothelial cells.

Avacopan (Tavneos™) is 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. Avacopan does not eliminate glucocorticoid use.

Avacopan is a complement 5a receptor (C5aR) antagonist that inhibits the interaction between C5aR and the anaphylatoxin C5a. Avacopan blocks C5a-mediated neutrophil activation and migration. The precise mechanism by which avacopan exerts a therapeutic effect in patients with ANCA-associated vasculitis has not been definitively established.

Policy:

INITIAL CRITERIA: Avacopan (Tavneos™) is approved when ALL of the following are met:

1. Diagnosis of one of the following types of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis:
    a. Granulomatosis with polyangiitis (GPA); or
    b. Microscopic polyangiitis (MPA); and
2. Member is receiving concurrent immunosuppressant therapy with one of the following:
    a. Cyclophosphamide; or
    b. Rituximab; and
3. One of the following:
    a. Member is concurrently on glucocorticoids (e.g., prednisone); or
    b. Inadequate response or inability to tolerate glucocorticoids (e.g., prednisone); and
4. Member is 18 years of age or older; and
5. Prescribed by or in consultation with one of the following:
    a. Nephrologist; or
    b. Pulmonologist; or

c. Rheumatologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Avacopan (Tavneos™) is re-approved when ALL of the following are met:

1. Member does not show evidence of progressive disease while on therapy; and
2. Member is receiving concurrent immunosuppressant therapy (e.g., azathioprine, cyclophosphamide, methotrexate, rituximab); and
3. Prescribed by or in consultation with one of the following:
   a. Nephrologist; or
   b. Pulmonologist; or
   c. Rheumatologist

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Pathogenesis of antineutrophil cytoplasmic autoantibody-associated vasculitis. UpToDate. October 2020. Available at: https://www.uptodate.com/contents/pathogenesis-of-antineutrophil-cytoplasmic-autoantibody-associated-vasculitis?search=antineutrophil%20cytoplasmic%20autoantibody%20associated%20vasculitis&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Accessed December 28, 2022.

Tavneos (avacopan) [package insert]. Cincinnati, OH. ChemoCentryx, Inc. Feburary 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7ea3c60a-45c7-44cc-afc2-d87fa53993c0&type=display. Accessed December 28, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Tavneos™	Avacopan

Cross References:

Rx.01.33 Off Label Use

Policy Version Number:	2.00
P&T Approval Date:	December 08, 2022
Policy Effective Date:	April 01, 2023

Next Required Review Date: December 08, 2023