Getting Patients Started on TAVNEOS®

Step-by-step guidance for your office to enroll patients in TAVNEOS® with confidence

TAVNEOS® (avacopan)

Patient Enrollment Form

Patient Enrollment Form

YOUR OFFICE: KEY ACTIONS

- Complete all sections of the form and include required medical documentation.
- Choose ONE TAVNEOS® Specialty Pharmacy (SP) and fax the completed form.

SPECIALTY PHARMACY (SP): WHAT TO EXPECT

- Contacts the patient within approximately one week to review coverage and, if eligible, enroll them in financial assistance.

The SP may call from an unknown number. Encourage patients to answer to avoid delays in therapy.

Quick Start Program

YOUR OFFICE: KEY ACTIONS

- The Quick Start Program provides a 15-day initial supply of TAVNEOS® at no cost to eligible patients when their insurance requires a prior authorization (PA) and their HCP believes a delay in therapy could lead to negative clinical outcomes.
- ***The Quick Start Program is only available by using the Patient Enrollment Form. If you think your patient may benefit, check the Quick Start box in Section 4.***

SPECIALTY PHARMACY (SP): WHAT TO EXPECT

- Contacts the patient by phone within 24 to 48 hours to confirm information and schedule delivery.

Patient communication is required. Please encourage patients to answer calls and save the SP phone number.

Prior Authorization & Appeals Support

A prior authorization (PA) may be required before your patient can start TAVNEOS®. The TAVNEOS® network SP can support your office throughout the PA and appeals process.

To support a successful submission:

- Confirm plan-specific criteria.
- Include diagnosis codes, prior treatments, and labs.
- Submit complete documentation.

If denied:

- Share the denial letter with the SP.
- Collaborate on next steps promptly.

For TAVNEOS®, some plans may assess coverage based on these criteria[1,2]:

Diagnosis codes to consider:

I77.82	ANCA-associated vasculitis (GPA or MPA)
I77.6	Unspecified arteritis
M31.3	Granulomatosis with polyangiitis (GPA)
M31.30	Granulomatosis with polyangiitis (GPA) without renal involvement
M31.31	Granulomatosis with polyangiitis (GPA) with renal involvement
M31.7	Microscopic polyangiitis (MPA)

Financial Support

YOUR OFFICE: KEY ACTIONS

- Inform eligible commercially insured patients about the TAVNEOS® co-pay program, which may reduce out-of-pocket costs to as little as $0.*

*Eligibility criteria and program maximums apply.
See TAVNEOSPro.com/copay for full Terms and Conditions.

SPECIALTY PHARMACY (SP): WHAT TO EXPECT

- Contacts the patient directly to complete enrollment.
- If ineligible for co-pay assistance or uninsured, helps identify other financial support options.

INDICATION: TAVNEOS (avacopan) 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. TAVNEOS does not eliminate glucocorticoid use.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: Serious hypersensitivity to avacopan or to any of the excipients.

Please see additional Important Safety Information on the next page.

Ongoing Support

Once approved, the SP remains your partner in supporting ongoing therapy.

The SP can:

- Contact patients monthly to schedule delivery.
- Encourage enrollment in text alerts for refill reminders.
- Help minimize therapy interruptions through timely communication.

Find additional HCP and patient resources and support at TAVNEOSPro.com.

Check TAVNEOS® prescription status any time by calling 1-833-TAVNEOS (1-833-828-6367)

Choose option 3

Biologics By McKesson

Choose option 2

PANTHERX RARE

REFERENCES

1. Cigna National Formulary Coverage Policy. Prior Authorization Policy Vasculitis – Tavneos® (avacopan capsules). Accessed April 10, 2026.
2. UnitedHealthcare. UnitedHealthcare Pharmacy Clinical Pharmacy Programs. Accessed April 10, 2026.

WARNINGS AND PRECAUTIONS

Hepatotoxicity: Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. In the postmarketing setting, vanishing bile duct syndrome (VBDS) as a consequence of liver injury, including cases with a fatal outcome, has been reported. These events occurred predominantly in Japan in patients aged 65 years and older, but VBDS may affect patients of any age or ethnicity who are receiving TAVNEOS. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for 6 months and as clinically indicated thereafter. For patients of Japanese descent, consider more frequent laboratory testing: every 2 weeks after the start of therapy for the first 3 months, followed by laboratory testing every 4 weeks for the next 3 months of treatment, and as clinically indicated thereafter. If a patient receiving treatment with TAVNEOS presents with an elevation in alanine aminotransferase [ALT] or aspartate aminotransferase [AST] to >3 times the upper limit of normal, evaluate promptly and consider pausing treatment as clinically indicated. If AST or ALT is > 5 times the upper limit of normal (ULN), or ALT or AST > 3 times the ULN with total bilirubin > 2 times the ULN, or alkaline phosphatase ≥ 2 times the ULN, or if the patient has clinical symptoms such as jaundice or pruritus, discontinue TAVNEOS until TAVNEOS-induced liver injury is ruled out. Immediately and permanently discontinue TAVNEOS if VBDS is suspected. TAVNEOS is not recommended for patients with active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risks and benefits before administering this drug to a patient with liver disease.

Serious Hypersensitivity Reactions: Cases of angioedema occurred in a clinical trial, including 1 serious event requiring hospitalization. Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be readministered unless another cause has been established.

Hepatitis B Virus (HBV) Reactivation: Hepatitis B reactivation, including life-threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for 6 months following. If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.

Serious Infections: Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS. The most common serious infections reported in the TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection, or who have been to places where certain infections are common.

ADVERSE REACTIONS

The most common adverse reactions (≥5% of patients and higher in the TAVNEOS group vs. prednisone group) were nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.

DRUG INTERACTIONS

Avoid co-administration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Consider dose reduction of CYP3A4 substrates when co-administering TAVNEOS. Co-administration of avacopan and 40 mg simvastatin increases the systemic exposure of simvastatin. While taking TAVNEOS, limit simvastatin dosage to 10 mg daily (or 20 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Consult the concomitant CYP3A4 substrate product information when considering administration of such products together with TAVNEOS.

TAVNEOS is available as a 10 mg capsule.

Please see Full Prescribing Information and Medication Guide for TAVNEOS.

To report a suspected adverse event, call 1-833-828-6367. You may report to the FDA directly by visiting www.fda.gov/medwatch or calling 1-800-332-1088.

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AMGEN