TAVNEOS® (avacopan)

# Your guide to prior authorizations*

*Specific plan requirements may vary; see important note below.

**A prior authorization (PA) may be required before your patient can start TAVNEOS®. This resource provides some suggestions on the information that health plans may need from you when submitting a PA.**

## How to submit a complete PA

Different payers have different PA forms, requirements, and submission criteria. Work with the TAVNEOS® network specialty pharmacy (SP) or check with your patient's health plan to obtain the appropriate form and to confirm the payer's requirements.

Always answer PA questions completely and provide supporting documentation. Include all relevant chart notes such as diagnosis codes, previous treatments, and labs.

### Before submitting the PA, be sure to confirm:

- ☐ The patient meets the health plan's criteria and you've included supporting documentation

### Common reasons for PA denials

These can include missing, incomplete, or outdated:

- Diagnosis details
- Chart notes
- Treatment history
- Labs

### 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 following pages.**

The information in this guide is for informational purposes only and does not guarantee coverage or reimbursement. Requirements and processes vary by payer and patient plan and may change without notice. Healthcare providers are responsible for selecting appropriate diagnosis and procedure codes and for verifying each plan's specific coverage, submission, and appeal requirements.

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

## Diagnosis codes to consider:

| | | |
|---|---|---|
| ☐ **I77.82** ANCA-associated vasculitis, ANCA-positive 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) | ☐ **Other** diagnosis code(s) _____ |

* GPA was formerly known as Wegener's granulomatosis.

† The diagnosis is related to ANCA-associated vasculitis, which includes GPA and MPA, and confirmed or awaiting confirmation using one or more lab tests: ANCA serum/biopsy/urinalysis.

## Other common criteria:

- Must be initiated in combination with standard therapy (e.g., cyclophosphamide, rituximab/rituximab biosimilar) and may include glucocorticoids
- Age ≥18 years old
- Prescribed by or in consultation with a specialist

## Some plans may also require:

- Lab tests—hepatitis testing, liver enzymes, estimated glomerular filtration rate (eGFR)
- Birmingham Vasculitis Activity Score (BVAS)
- Kidney biopsy
- Positive test for myeloperoxidase (MPO)- or proteinase 3 (PR3)-ANCA

## Did you know?

- ANCA-associated vasculitis is a group of rare diseases involving inflammation of small- to medium-sized blood vessels.[3-5]
- Adjunctive therapy is a therapy given in addition to the primary or main therapy.[6]
- Antineutrophil cytoplasmic antibodies (ANCAs) are autoantibodies. MPO and PR3 are the two major antigens targeted by ANCAs in patients with MPA or GPA. ANCA testing detects the presence or absence of these auto-antibodies in the blood by indirect immunofluorescence or enzyme-linked immunoassay.[7]
- The BVAS is a validated tool and the most widely accepted measure of disease activity in major studies of vasculitis.[8]

## IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS AND PRECAUTIONS

**Hepatotoxicity:** Serious cases of hepatic injury have been observed in patients taking TAVNEOS®, including life-threatening events. Obtain liver test panel before initiating TAVNEOS®, every 4 weeks after start of therapy for 6 months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). 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.

**Please see additional Important Safety Information on the following pages.**

## Initial PA approval typically covers access for 6 to 12 months depending on the health plan[1,2]

- Refer to the approval letter to find the approval period
- Renewal often requires that initial criteria are met, and that the medication is providing clinical benefit

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# PA denied? You may have options

## If a PA is denied, your patient may still be able to access the medicine they need. There are often multiple paths forward.

**All health plans must issue a denial letter explaining why the PA was denied. You may be able to resubmit the PA or appeal the decision to address the reasons for the denial stated in the letter.**

### Resubmit

**Many plans allow the PA to be resubmitted if there is an administrative error (incorrect diagnosis code, missing information) or if new information is available (labs, clinical notes)** that was not originally submitted. Specify in the resubmission what new information has been attached for reconsideration.

### Appeal

**Closely review the details of the denial letter to understand:**

- Why the PA was denied
- What additional documentation is required
- Where to send the appeal and how long you have to appeal

**Appeal steps may include:**

- Requesting an independent medical reviewer or a specialty peer-to-peer review
- Providing a sample letter of appeal for coverage (see sample letter available at TAVNEOSPro.com)

### Sample letter of appeal for coverage

**TAVNEOSPro.com**
Resources for Your Practice

### For any questions, call the TAVNEOS® Team

1-833-TAVNEOS
(833-828-6367)
Monday-Friday from
8 am-8 pm ET

### IMPORTANT SAFETY INFORMATION (CONT'D)

### WARNINGS AND PRECAUTIONS (CONT'D)

**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.

**Please see additional Important Safety Information on the following pages.**

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## IMPORTANT SAFETY INFORMATION (CONT'D)

### 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 coadministration of TAVNEOS® with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS® dose when coadministered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Monitor for adverse reactions and consider dose reduction of certain sensitive CYP3A4 substrates.

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.

## REFERENCES


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3. Berti A, Dejaco C. Update on the epidemiology, risk factors, and outcomes of systemic vasculitides. *Best Pract Res Clin Rheumatol*. 2018;32(2):271-294.
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