TAVNEOS® (avacopan)

Your guide to TAVNEOS® prior authorizations*

*Specific plan requirements may vary

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

Remember that different payers have different PA forms, requirements, and submission criteria. Work with the 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These can include missing, incomplete, or outdated: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.

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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 is 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 a standard therapy regimen that includes either cyclophosphamide or rituximab/rituximab biosimilar, plus glucocorticoids
- Age ≥ 18 years old
- Prescribed by or in consultation with a specialist

Some plans may also require:

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

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.

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]
- MPO and PR3 are the two major targeted antigens in patients with GPA or MPA.[7] ANCA testing detects the presence or absence of these autoantibodies to MPO or PR3 in the blood by looking at the pattern of fluorescence on a slide under a microscope or ELISA assay.[8]
- BVAS is a comprehensive multisystem clinical assessment used primarily in therapeutic studies of systemic vasculitis to assess disease activity.[9]

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 new information 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 letter of medical necessity (see sample letter available by scanning the QR code to the right)

Sample letter of medical necessity

tavneospro.com
under HCP Resources

For any questions, call the TAVNEOS® Connect Team

Monday-Friday from 8 am—8 pm ET at 1-833-TAVNEOS (833-828-6367) and choose option 2, then 1

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 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 accompanying 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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