Supporting your TAVNEOS® (avacopan) patients from inpatient to outpatient

Starting: In the in-patient setting

- Order TAVNEOS **through the inpatient hospital pharmacy**.
- **Amgen offers TAVNEOS in a 5-day supply**, since the average expected hospital stay for patients on TAVNEOS is 5 to 10 days.
- The wholesale acquisition cost (WAC) price for a 5-day supply is [$2,757,90]
- TAVNEOS will typically be delivered the **next business day**.

TAVNEOS Specialty Distributor Network

- Contact these Specialty Distributors directly to order TAVNEOS for the inpatient pharmacy.

ASD Healthcare (AmerisourceBergen)
Phone: (800) 746-6273
Fax: (800) 547-9413
Email: service@asdhealthcare.com
Online: www.asdhealthcare.com

Cardinal Health Specialty Pharmaceutical Distribution (SPD)
Phone: (866) 476-1340
Email: GMB-SPD-CSOrderEntry@cardinalhealth.com
Online: orderexpress.cardinalhealth.com

McKesson Plasma and Biologics
Phone: (877) 625-2566
Fax: (888) 752-7626
Email: mpborders@mckesson.com
Online: connect.mckesson.com

Transitioning: To the outpatient setting

- To avoid disruption of therapy, the **TAVNEOS Quick Start Program** provides eligible patients being discharged from the inpatient setting with up to a 30-day supply of TAVNEOS.
  - Request Quick Start as soon as possible to help your patient be enrolled prior to discharge and obtain a supply promptly delivered to their home.
  - Scan the QR code or visit TAVNEOSpro.com to download the Patient Enrollment Form. Complete the Quick Start section in its entirety. Be sure to include office **"Contact Name"** and **"Contact's Phone"** to ensure prompt communication and support.
  - Fax the completed Patient Enrollment Form to the hub team at 1-833-200-7366.
  - Once approved by the TAVNEOS team, eligible patients or their authorized contact will be contacted to **set up delivery to their home**. The pharmacy must speak to the patient or authorized contact to confirm shipping.
  - After, the TAVNEOS team will triage the referral to a network pharmacy to **help advance the insurance approval process**.

TAVNEOS Product Information

Product

Images not shown at actual size

10 mg, opaque, yellow and light orange capsule with CCX168 printed in black

NDC	73556-168-01 (180 count) 73556-168-02 (30 count)
Strength	10 mg
Form	Capsule
Dosing	3 capsules by mouth, twice daily, with food

For any questions, call the TAVNEOS team

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

To request a representative, go to TAVNEOSpro.com/contact

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.

TAVNEOS® (avacopan)

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.

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.

Reference: TAVNEOS [package insert]. Cincinnati, OH: Amgen Inc.

TAVNEOS® (avacopan)

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