



Commercial/Healthcare Exchange PA Criteria

Effective: December 9th 2021

Prior Authorization: Tavneos™

Products Affected: Tavneos (avacopan) capsules

Medication Description: 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.

Covered Uses: 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. Tavneos does not eliminate glucocorticoid use.

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Medical History

Age Restrictions: ≥ 18 years of age

Prescriber Restrictions: Tavneos to be prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist

Coverage Duration:

Initial: 6 months

Reauthorization: 12 months

Other Criteria:

I. Initial Criteria

1. Anti-Neutrophil Cytoplasmic Autoantibody (ANCA)-Associated Vasculitis. Approve for the duration noted if the patient meets **ONE** of the following criteria (A **or** B):

A. **Initial Therapy.** Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v **and** vi):

- i. Patient is ≥ 18 years of age; **AND**
- ii. Patient has granulomatosis with polyangiitis or microscopic polyangiitis; **AND**
Note: Granulomatosis with polyangiitis is also known as Wegener's granulomatosis.
- iii. Patient has active disease; **AND**

Note: This includes patients that have newly diagnosed or relapsed disease. This does **not** include patients already in remission.

Last Rev. December 2021



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- iv. Patient is positive for proteinase 3 antibodies, myeloperoxidase antibodies, or anti-neutrophil cytoplasmic autoantibody (ANCA); **AND**
- v. Patient is using this medication in combination with at least one immunosuppressant; **AND**
- vi. The medication is prescribed by or in consultation with a rheumatologist, nephrologist, or immunologist.
- B. Patient is Currently Receiving Tavneos. Approve for 1 year if the patient meets ALL of the following criteria (i, ii **and** iii):
 - i. Patient is ≥ 18 years of age; **AND**
 - ii. Patient has been established on Tavneos for at least 6 months; **AND**
 - iii. Patient meets at least one of the following (a **or** b):
 - a. When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating Tavneos); **OR**
Note: Examples of objective measure include improvement in estimated glomerular filtration rate, decrease in urinary albumin creatinine ratio, or improvement in the Birmingham Vasculitis Activity Score [BVAS].
 - b. Compared with baseline (prior to receiving Tavneos), patient experienced an improvement in at least one symptom, such as joint pain, ulcers, myalgia, persistent cough, skin rash, abdominal pain, or improvement in function or activities of daily living.

References:

1. Tavneos [prescribing information]. San Carlos, CA, ChemoCentryx Inc; October 2021.
2. Tavneos. IBM Micromedex® [database online]. Greenwood Village, CO. Truven Health Analytics. Available at: <https://www.micromedexsolutions.com>. Updated November 3, 2021. Accessed November 17, 2021.
3. Jayne DRW, Merkel PA, Schall TJ, et al. Avacopan for the treatment of ANCA-associated vasculitis. *N Engl J Med.* 2021;384(7):599-609.
4. Chung S, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation guidelines for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis Care and Research.* 2021; 73(8):1088-1105

Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/9/2021