Reference number(s)
5019-A

Specialty Guideline Management
Tavneos

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tavneos	avacopan

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

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.

All other indications are considered experimental/investigational and not covered benefits.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

Initial requests

- Chart notes or medical records showing a history of positive serum assay for anti-proteinase-3 (anti-PR3) or anti-myeloperoxidase (anti-MPO) antibody
- Chart notes or medical records of pre-treatment objective assessment of the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic)

Continuation requests

Chart notes or medical records showing stabilization or improvement in the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic)

Coverage Criteria

Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA])[1-4]

Authorization of 12 months may be granted for treatment of severe active ANCA-associated vasculitis (GPA and MPA) when all of the following criteria are met:

- Tavneos will be used in combination with standard therapy (e.g., rituximab, cyclophosphamide, methotrexate, azathioprine, mycophenolate mofetil)
- The member has a history of testing positive for anti-PR3 or anti-MPO antibody
- Documentation of pretreatment objective assessment of the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic)

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment for severe active ANCA-associated vasculitis (GPA and MPA) in members who achieve or maintain a positive clinical response as evidenced by stabilization or improvement in the most impactful aspects of the member's ANCA-associated vasculitis (e.g., renal, pulmonary, neurologic).

References

1. Tavneos [package insert]. Cincinnati, OH: ChemoCentryx, Inc.; June 2024.
2. Chung SA, Langford CA, Maz M, et al. 2021 American college of rheumatology/vasculitis foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. Arthritis Rheumatol. 2021 Aug;73(8):1366-1383.

3. Geetha D, Jefferson JA. ANCA-Associated vasculitis: Core curriculum 2020. Am J Kidney Dis. 75(1):124-137.
4. Jayne DRW, Merkel PA, Schall TJ, Bekker Pl. Avacopan for the treatment of ANCA-associated vasculitis [supplemental appendix]. N Engl J Med. 2021; 384:599-609. doi: 10.1056/NEJMoa2023386.