CVS Caremark®

|  |
| --- |
| 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 Indications1

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.