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Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
Policy Number: C22223-A

Tavneos (avacopan)

PRODUCTS AFFECTED

Tavneos (avacopan)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY ASSOCIATED VASCULITIS:
   1. Documented diagnosis of active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated

vasculitis
AND

2. Documentation of all of the following: a) a positive test for either anti- proteinase 3 (PR3) or anti-myeloperoxidase (MPO) AND b) At least 1 major item, 3 non-major items, or 2 renal items of proteinuria and hematuria on the Birmingham Vasculitis Activity Score (see Appendix)
   AND
3. Prescriber attests to the following: (a) obtaining liver test panel before initiating Tavneos (avacopan) therapy AND (b) screening the member for hepatitis B infection by measuring HBsAg and anti-HBc
   AND
4. Documentation that member is currently receiving standard therapy with cyclophosphamide or rituximab with or without glucocorticoids
   AND
5. Prescriber attests Tavneos (avacopan) will be used in combination with standard therapy
   AND
6. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal (e.g., glucocorticoid dose, renal function, etc.) [DOCUMENTATION REQUIRED]
   AND
7. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Tavneos (avacopan) include: Serious hypersensitivity to avacopan or to any of the excipients, avoid use in patients with active serious infections including localized infections, and avoid use with strong and moderate CYP3A4 enzyme inducers (e.g., rifampin).]

CONTINUATION OF THERAPY:

A. ANTI-NEUTROPHIL CYTOPLASMIC AUTOANTIBODY ASSOCIATED VASCULITIS:
   1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
      AND
   2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity (e.g., elevated liver transaminases)
      AND
   3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms (e.g., improved or sustained renal function and/or ability to decrease their current glucocorticoid dose, BVAS score/items etc.)
      AND
   4. Prescriber attests member is currently receiving standard therapy with cyclophosphamide or rituximab with or without glucocorticoids

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with a board-certified rheumatologist, nephrologist, hematologist or immunologist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

18 years of age and older

QUANTITY:
30mg twice daily

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Complement C5a Receptor Inhibitors

FDA-APPROVED USES:
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.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
BVAS Assessment Training Manual.pdf (vcrc.rarediseasesnetwork.org)

Major items include:

- Gangrene
- Scleritis/Episcleritis
- Retinal changes (vasculitis/thrombosis/exudate/hemorrhage)
- Sensorineural hearing loss
- Massive hemoptysis/alveolar hemorrhage
- Respiratory failure
- Ischemic abdominal pain
- Rise in serum creatinine >30% or fall in creatinine clearance >25%
- Meningitis
- Cerebrovascular accident
- Spinal cord lesion
- Cranial nerve palsy
- Sensory peripheral neuropathy
- Mononeuritis multiplex
- RBC casts and/or glomerulonephritis

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis is a progressive autoimmune systemic disease characterized by the inflammation and destruction of small- to medium-sized blood vessels resulting in organ damage and failure. The major disorders under the ANCA-associated vasculitis umbrella include the following:

- **Microscopic polyangiitis (MPA):** a necrotizing vasculitis predominantly affecting the capillaries, venules, or arterioles. Almost all patients with MPA have kidney manifestations with or without some pulmonary involvement. Approximately 90% of MPA patients have ANCA autoantibodies present.
- **Granulomatosis with polyangiitis (GPA):** primarily affects capillaries, venules, arterioles, arteries, and veins. Patients with GPA experience inflammation in the upper and lower respiratory tract as well as a pauci-immune glomerulonephritis, which is a rapidly progressive condition leading to renal failure within days to weeks. Some patients will require dialysis at the time of diagnosis. Approximately 80% of GPA patients have ANCA autoantibodies present.
- **Eosinophilic granulomatosis with polyangiitis (EGPA):** EGPA is also known as Churg-Strauss syndrome and is an eosinophilic-rich necrotizing vasculitis. Patients generally experience chronic rhinosinusitis, asthma, and peripheral blood eosinophilia. Only 40% of patients with EGPA have ANCA autoantibodies present.

Tavneos™ (avacopan) is a first-in-class, orally administered, small molecule designed to selectively block the complement 5a receptor (C5aR) on destructive inflammatory cells such as blood neutrophils. The Food and Drug Administration approved Tavneos as an adjunctive treatment for adults with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis and microscopic polyangiitis) in combination with standard therapy including glucocorticoids.

The approval was based on data from the double-blind, active-controlled phase 3 ADVOCATE trial (ClinicalTrials.gov Identifier: NCT02994927), which evaluated the efficacy and safety of avacopan in 330 adults with newly diagnosed or relapsed ANCA-associated vasculitis. Patients were randomly assigned 1:1 to receive either avacopan 30mg twice daily or prednisone. All patients received either rituximab or cyclophosphamide, followed by azathioprine or mycophenolate. The co-primary endpoints were disease remission at week 26 and sustained disease remission at week 52.

Findings showed that 72.3% of avacopan-treated patients achieved disease remission (as assessed by Birmingham Vasculitis Activity Score) at week 26 compared with 70.1% of prednisone- treated patients, establishing noninferiority of the investigational treatment (P <.0001). At week 52, avacopan demonstrated statistical superiority in sustained remission compared with prednisone (65.7% vs 54.9%, respectively; P =.013).

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Tavneos (avacopan) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tavneos (avacopan) include: Serious hypersensitivity to avacopan or to any of the excipients, avoid use in patients with active serious infections including localized infections, and avoid use with strong and moderate CYP3A4 enzyme inducers (e.g., rifampin).

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document.*

Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Tavneos CAPS 10MG

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Quantity References	Q4 2023

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file