Reference number(s)
5019-A

SPECIALTY GUIDELINE MANAGEMENT

TAVNEOS (avacopan)

POLICY

I. 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 Indication
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.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Initial requests:
   1. Chart notes or medical records showing positive serum assay for Proteinase-3 (PR3) or myeloperoxidase (MPO) antibody
   2. Chart notes or medical records of pre-treatment Birmingham Vasculitis Activity Score (BVAS) version 3
   3. Chart notes or medical records of at least one major item, or at least three non-major items, or at least two renal items of hematuria and proteinuria present on BVAS version 3 (refer to Appendix)
B. Continuation requests: Chart notes or medical records showing stabilization or improvement in the BVAS version 3

III. CRITERIA FOR INITIAL APPROVAL

Anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA])
Authorization of 12 months may be granted for treatment of severe active ANCA-associated vasculitis (GPA and MPA) when all of the following are met:
A. Tavneos will be used in combination with standard therapy (e.g. cyclophosphamide, azathioprine, mycophenolate, rituximab)
B. The member is positive for anti-PR3 or anti-MPO
C. Pre-treatment Birmingham Vasculitis Activity Score (BVAS) version 3 demonstrates the presence of at least one major item, or at least three non-major items, or at least two renal items of hematuria and proteinuria (refer to Appendix)

IV. 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 positive clinical response as evidenced by stabilization or improvement in the BVAS.

V. APPENDIX

Birmingham Vasculitis Activity Score (version 3)

*****Major items are indicated in bold italics

General • Myalgia • Arthralgia/ arthritis • Fever ≥ 38 °C • Weight loss ≥ 2 kg	Cardiovascular • Loss of pulses • Valvular heart disease • Pericarditis • Ischemic cardiac pain • Cardiomyopathy • Congestive cardiac failure
Cutaneous • Infarct • Purpura • Ulcer • ***Gangrene*** • Other skin vasculitis	Abdominal • Peritonitis • Bloody diarrhea • ***Ischemic abdominal pain***
Mucous membranes/ eyes • Mouth ulcers • Genital ulcers • Adnexal inflammation • Significant proptosis • ***Scleritis/ Episcleritis*** • Conjunctivitis/ Blepharitis/ Keratitis • Blurred vision • Sudden vision loss • Uveitis • ***Retinal changes (vasculitis/ thrombosis/ exudate/ hemorrhage***	Renal • Hypertension • Proteinuria > 1+ or > 0.2 g/g creatinine • Hematuria ≥ 10 RBCs/hpf • Serum creatinine 125-249 µmol/L (1.41-2.82 mg/dL) • Serum creatinine 250-499 µmol/L (2.83-5.64 mg/dL) • Serum creatinine ≥ 500 µmol/L (5.65 mg/dL) • ***Rise in serum creatinine > 30% or fall in creatinine clearance > 25%***
Ear Nose & Throat • Bloody nasal discharge/ crusts/ ulcers/ granulomata • Paranasal sinus involvement • Subglottic stenosis • Conductive hearing loss • ***Sensorineural hearing loss***	Nervous System • Headache • ***Meningitis*** • Seizures (not hypertensive) • ***Cerebrovascular accident*** • Organic confusion • ***Spinal cord lesion*** • ***Cranial nerve palsy*** • ***Sensory peripheral neuropathy*** • ***Mononeuritis multiplex***
Chest • Wheeze • Nodules or cavities • Pleural effusion/ pleurisy	Other • ***RBC casts and/or glomerulonephritis***

• Infiltrate • Endobronchial involvement • ***Massive hemoptysis/ alveolar hemorrhage*** • ***Respiratory failure***	

VI. REFERENCES

1. Tavneos [package insert]. Cincinnati, OH: ChemoCentryx, Inc.; October 2021.
2. American College of Rheumatology. 2021 American college of rheumatology/vasculitis foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis & Rheumatology.* Https://www.vasculitisfoundation.org/wp-content/uploads/2021/07/2021-ACR-VF-Guideline-for-Management-of-ANCA-Associated-Vasculitis.pdf. Accessed October 21, 2021.
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 et al. Avacopan for the treatment of ANCA-associated vasculitis [supplemental appendix]. *N Engl J Med.* 2021; 384:599-609. DOI: 10.1056/NEJMoa2023386. https://www.nejm.org/doi/suppl/10.1056/NEJMoa2023386/suppl_file/nejmoa2023386_appendix.pdf. Accessed October 28, 2021.