

# Tavneos (avacopan)

| Override(s)                           | Approval Duration  |
|---------------------------------------|--|
| Prior Authorization<br>Quantity Limit | 1 year per lifetime<br><br><i>Note: There is insufficient evidence to support the use of Tavneos (avacopan) for continuation and/or for retreatment beyond one (1) year.</i> |

| Medications        | Quantity Limit                   |
|--------------------|----------------------------------|
| Tavneos (avacopan) | May be subject to quantity limit |

## APPROVAL CRITERIA

Initial requests for Tavneos (avacopan) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Tavneos (avacopan) is prescribed by or in consultation with a rheumatologist or nephrologist; **AND**
- III. Documentation is provided that individual has a diagnosis of one of the following:
  - A. Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis with severe, active Granulomatosis with Polyangiitis (GPA); **OR**
  - B. Antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis with severe, active Microscopic Polyangiitis (MPA);

### **AND**

- IV. Individual is using in combination with cyclophosphamide or rituximab; **AND**
- V. Individual is using with or without glucocorticoids.

## Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. FDA Briefing Document. Arthritis Advisory Committee Meeting. 2021. NDA# 214487 Drug name: avacopan. Available at: <https://www.fda.gov/media/148176/download>. Accessed November 17, 2022.
5. Chung, Sharon A et al. "2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis." *Arthritis & rheumatology (Hoboken, N.J.)* vol. 73,8 (2021): 1366-1383. doi:10.1002/art.41773

6. Hellmich, Bernhard et al. "EULAR recommendations for the management of ANCA-associated vasculitis: 2022 update." *Annals of the rheumatic diseases*, ard-2022-223764. 16 Mar. 2023, doi:10.1136/ard-2022-223764
7. Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. *N Engl J Med* 2021 Feb 18;384(7):599-609.
8. Tavneos (avacopan) {prescribing information}. Cincinnati, OH: ChemoCentryx; October 2021.
9. Yates M, Watts RA, Bajema IM, et al. EULAR/ERA-EDTA recommendations for the management of ANCA-associated vasculitis. *Annals of the Rheumatic Diseases* 2016;75:1583-1594.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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