

Avacopan (Tavneos)

Coverage Criteria:

Initial Authorization Criteria:

Tavneos is reserved for:

- 1. Prescribed by specialist (rheumatologist, nephrologist, pulmonologist, or cardiologist); AND,
- 2. Patient has been diagnosed with ANCA vasculitis (either granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]), confirmed by:
 - a. characteristic clinical findings (small vessel vasculitis of the ear, nose, throat, airways, lungs, kidneys, skin, eyes or peripheral nervous system); AND,
 - b. laboratory test (positive for ANCA [MPO or PR3 subtypes]); AND,
 - c. imaging studies; AND,
- 3. Patient has inadequate disease control despite at least 12 weeks of therapy with rituximab; AND,
- 4. Patient has inadequate disease control despite at least 12 weeks of therapy with at least one of the following:
 - a. Cyclophosphamide; OR,
 - b. Methotrexate; OR,
 - c. Azathioprine; OR,
 - d. Mycophenolate mofetil; OR,
 - e. Leflunomide; AND,
- 5. Provider attests that patient is to continue glucocorticoid therapy as tolerated and needed during treatment with Tavneos; AND,
- 6. Prescribed per FDA dosing regimen.

Renewal Criteria:

- 1. Patient continues to meet the criteria above; AND,
- 2. Patient has been seen and evaluated by prescriber in the past 14 months; AND,
- 3. Patient has had a clinically meaningful response to therapy (defined as a reduction in glucocorticoid use, or sustained remission while on Tavneos therapy). Chart notes must be submitted with renewal requests; AND,
- 4. Prescribed per FDA dosing regimen.

Coverage Duration:

Initial authorization will be provided for 3 months. Re-authorizations will be provided for 6 months.