



Tavneos (avacopan) Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
3/1/2023

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Tavneos	avacopan cap	10 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Days Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist	Effective Date
Tavneos	Avacopan Cap	10 MG	180.0	CAPS	30	Days				

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tavneos	avacopan cap	10 MG	Commercial ; HIM ; ResultsRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tavneos	Avacopan Cap	10 MG	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days OR

Module	Clinical Criteria for Approval
	<p>B. The prescriber states the patient has been treated with the requested agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy is changed OR</p> <p>C. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and/or microscopic polyangiitis [MPA]) AND 2. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted OR <p>D. BOTH of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA approved indication for the requested agent AND 2. The patient has been screened for prior or current hepatitis B infection AND if positive a prescriber specializing in hepatitis B treatment has been consulted AND <p>2. ONE of the following:</p> <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication AND <p>3. The patient does NOT have severe hepatic impairment (Child-Pugh C) AND</p> <p>4. BOTH of the following:</p> <ol style="list-style-type: none"> A. The patient is currently treated with standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) for the requested indication AND B. The patient will continue standard therapy (e.g., cyclophosphamide, rituximab, azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication AND <p>5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval: 6 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process AND 2. The patient has had clinical benefit with the requested agent AND 3. The patient does NOT have severe hepatic impairment (Child-Pugh C) AND 4. BOTH of the following: <ol style="list-style-type: none"> A. The patient is currently treated with standard therapy (e.g., azathioprine, mycophenolate mofetil) for the requested indication AND B. The patient will continue standard therapy (e.g., azathioprine, mycophenolate mofetil) in combination with the requested agent for the requested indication AND 5. The prescriber is a specialist in the area of the patient's diagnosis (e.g., rheumatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 6. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval: 12 months</p> <p>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria section below.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none">1. The requested quantity (dose) does NOT exceed the program quantity limit OR2. ALL of the following:<ol style="list-style-type: none">A. The requested quantity (dose) is greater than the program quantity limit ANDB. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication ANDC. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR3. ALL of the following:<ol style="list-style-type: none">A. The requested quantity (dose) is greater than the program quantity limit ANDB. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication ANDC. The prescriber has provided information in support of therapy with a higher dose for the requested indication <p>Length of approval: Initial approval - 6 months; Renewal approval - 12 months</p>