



Tarpeyo Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
11-01-2025

Date of Origin
06-07-2022

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Tarpeyo	budesonide delayed release cap	4 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	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Tarpeyo	Budesonide Delayed Release Cap	4 MG	120	Capsules	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tarpeyo	budesonide delayed release cap	4 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Tarpeyo	Budesonide Delayed Release Cap	4 MG	IL HMO Performance Annual ; Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<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 a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy AND 2. The requested agent will be used to reduce the loss of kidney function in a patient at risk for disease progression AND 3. ONE of the following: <ol style="list-style-type: none"> A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.44 g/g OR B. The patient has proteinuria greater than or equal to 0.5 g/day AND 4. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m² AND 5. If the patient has an FDA labeled indication, then ONE of the following: <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. There is support for using the requested agent for the patient's age for the requested indication AND 6. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response after at least a 3 month duration of therapy with a maximally tolerated angiotensin-converting enzyme inhibitor (ACEi, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEi or ARB OR B. An intolerance or hypersensitivity to an ACEi or ARB OR C. An FDA labeled contraindication to ALL ACEi and ARB AND 7. ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR C. The patient has tried and had an inadequate response to ONE oral generic glucocorticoid [chart notes required] OR D. ONE oral generic glucocorticoid was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR

Module	Clinical Criteria for Approval
	<p>E. The patient has an intolerance or hypersensitivity to ONE oral generic glucocorticoid that is not expected to occur with the requested agent [chart notes required] OR</p> <p>F. The patient has an FDA labeled contraindication to ALL oral generic glucocorticoids that is not expected to occur with the requested agent [chart notes required] OR</p> <p>G. ONE oral generic glucocorticoid is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient’s adherence of care; OR worsen a comorbid condition; OR decrease the patient’s ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>H. ONE oral generic glucocorticoid is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>I. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE oral generic glucocorticoid and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>8. ONE of the following:</p> <p>A. The patient has not previously been treated with a course of therapy (9 months) with the requested agent OR</p> <p>B. The patient has previously been treated with a course of therapy with the requested agent, AND there is support for an additional course of therapy with the requested agent AND</p> <p>9. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND</p> <p>10. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months ALL other plans: 10 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit criteria.</p> <p>The requested agent will also be approved when ALL of the following are met:</p> <p>1. The member resides in Ohio AND</p> <p>2. The plan is Fully Insured or HIM Shop (SG) AND</p> <p>3. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>4. ONE of the following:</p> <p>A. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>B. The patient has another indication that is supported in compendia for the requested agent and route of administration OR</p> <p>C. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p>

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	<p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</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 OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit OR C. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSIL: 12 months All other plans: 10 months</p>