

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2025 P 2268-6
Program	Prior Authorization/Medical Necessity
Medication	Tarpeyo® (budesonide delayed-release capsules)
P&T Approval Date	2/2022, 4/2022, 7/2022, 7/2023, 2/2024, 2/2025
Effective Date	5/1/2025

**1. Background:**

Tarpeyo (budesonide delayed-release capsule) is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

**2. Coverage Criteria<sup>a</sup>:**

<p><b>A. Authorization</b></p> <p>1. Tarpeyo will be approved based on <b>all</b> of the following:</p> <p style="padding-left: 40px;">a. Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">b. Patient is at risk for disease progression</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">c. Used to reduce the loss of kidney function</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">d. Estimated glomerular filtration rate (eGFR) <math>\geq</math> 35 mL/min/1.73 m<sup>2</sup></p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">e. <b>One</b> of the following:</p> <p style="padding-left: 80px;">1) Patient is on a stabilized dose and receiving concomitant therapy with <b>one</b> of the following:</p> <p style="padding-left: 120px;">a) maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g. captopril, enalapril)</p> <p style="padding-left: 120px;">b) maximally tolerated angiotensin II receptor blocker (ARB) (e.g. candesartan, valsartan)</p> <p style="text-align: center;"><b>-OR-</b></p>
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<p>2) Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARB</p> <p style="text-align: center;"><b>-AND-</b></p> <p>f. History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>g. Prescribed by or in consultation with a nephrologist</p> <p><b>Authorization will be issued for 9 months</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; June 2024
2. KDIGO 2021 Glomerular Diseases Guideline. October 2021; 100 (4S).

Program	Prior Authorization/Medical Necessity – Tarpeyo
<b>Change Control</b>	
Date	Change
2/2022	New program
4/2022	Removed Immunologist prescriber requirement and updated urine protein-to-creatinine ratio (UPCR) of $\geq 1.5$ g/g to be an example along with the International IgAN Prediction Tool.
7/2022	Added requirement of IgAN confirmed by renal biopsy and a 30-day trial of a glucocorticoid.
7/2023	Annual review. No changes.
2/2024	Updated indication and removed example for disease progression. Updated references.
2/2025	Annual review. Updated references.