UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2268-4
Program	Prior Authorization/Medical Necessity
Medication	Tarpeyo (budesonide delayed-release capsules)
P&T Approval Date	2/2022, 4/2022, 7/2022, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

1. Background:

Tarpeyo (budesonide delayed-release capsule) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Tarpeyo slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

2. Coverage Criteria[a]:

A. Authorization

1. Tarpeyo will be approved based on **all** of the following:

   a. Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

   -AND-

   b. Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

   -AND-

   c. Used to reduce proteinuria

   -AND-

   d. Estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m2

   -AND-

   e. **One** of the following:

      1) Patient is on a stabilized dose and receiving concomitant therapy with **one** of the following:

a) maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g. captopril, enalapril)
b) maximally tolerated angiotensin II receptor blocker (ARB) (e.g. candesartan, valsartan)

-OR-

2) Patient has an allergy, contraindication, or intolerance to ACE inhibitors and ARB

-AND-

f. History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)

-AND-

g. Prescribed by or in consultation with a nephrologist

Authorization will be issued for 9 months

[a] 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.

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, Sweedem: Calliditas Therapeutics AB; December 2021.
2. KDIGO 2021 Glomerular Diseases Guideline. October 2021; 100 (4S).

Program	Prior Authorization/Medical Necessity – Tarpeyo
Change Control	
Date	Change
2/2022	New program
4/2022	Removed Immunologist prescriber requirement and updated urine protein-to-creatinine ratio (UPCR) of ≥ 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.