UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2268-5
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
Effective Date	5/1/2024

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[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 for disease progression

   -AND-

   c. Used to reduce the loss of kidney function

   -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 2023.
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.
2/2024	Updated indication and removed example for disease progression. Updated references.