VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Nephrology – Tarpeyo Prior Authorization Policy
- Tarpeyo™ (budesonide delayed-release capsules – Calliditas)

REVIEW DATE: 01/05/2022; selected revision 01/19/2022

OVERVIEW

Tarpeyo, a corticosteroid, 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.[1] 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.

The recommended dose is 16 mg orally once daily (QD) at least 1 hour before a meal for 9 months.[1] When discontinuing therapy, the dose is reduced to 8 mg QD for the last 2 weeks of therapy. Safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.

Clinical Efficacy

The efficacy of Tarpeyo was evaluated in one pivotal, 9-month trial in patients ≥ 18 years of age with IgAN.[1] Eligible patients had biopsy-proven IgAN, estimated glomerular filtration rate (eGFR) ≥ 35 mL/min/1.73 m^2 and ≤ 90 mL/min/1.73 m^2, and proteinuria (defined as either ≥ 1 g/day or UPCR ≥ 0.8 g/g).[1,2] Patients were also receiving a stable dose of maximally tolerated renin angiotensin system (RAS) inhibitor therapy for ≥ 3 months.[1,2] Tarpeyo resulted in statistically greater reduction in UPCR and less eGFR decline relative to placebo after 9 months of treatment.

Guidelines

Tarpeyo is recognized as new therapy "in development" for high-risk IgAN patients by the Kidney Diseases Improving Global Outcomes (KDIGO) guidelines for the management of glomerular diseases (2021).[4] According to the guidelines, a number of new therapies for high-risk IgAN patients are being evaluated that may augment the supportive care approach or more specific approaches (e.g., Tarpeyo, various complement inhibitors, and therapies targeting B-cell development).

Following biopsy-confirmed diagnosis of IgAN, the guidelines recommend assessment of disease progression.[4] The primary focus of IgAN treatment should include multiple modalities such as RAS blockage (maximum dose or maximum tolerated dose), blood pressure control, cardiovascular risk minimization, and adherence to lifestyle advice (i.e., dietary counseling, smoking cessation, weight control, and exercise as appropriate). When proteinuria remains > 0.75 to 1.0 g/day despite ≥ 90 days of optimized supportive care, the patient has a high risk of progressive loss of kidney function and may be considered for a 6-month course of steroid therapy (recently cited trials include prednisone or methylprednisolone), or preferably the opportunity to take part in a clinical trial.[4] Guidelines point out that the clinical benefit of steroids in IgAN is not established, and should be used with extreme caution or avoided in patients with eGFR < 30 mL/min/1.73 m^2, diabetes, obesity (body mass index > 30 kg/m^2), latent infections (e.g., tuberculosis, viral hepatitis), secondary disease (e.g., cirrhosis), active peptic ulceration, uncontrolled psychiatric illness, and severe osteoporosis. There are no data to support the efficacy or reduced toxicity of alternate day steroid regimens or dose-reduced protocols.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Tarpeyo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tarpeyo as well as the monitoring required for adverse events and long-term efficacy, approval requires Tarpeyo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Tarpeyo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Primary Immunoglobulin A Nephropathy.** Approve for the duration noted if the patient meets ONE of the following criteria (A or B):
   - **A)** Initial Therapy. Approve for 10 months if the patient meets the following criteria (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** Patient is at high risk of disease progression, defined by meeting the following criteria (a and b):
       - **a)** Patient meets ONE of the following ([1] or [2]):
         - **(1)** Proteinuria > 0.75 g/day; OR
         - **(2)** Urine protein-to-creatinine ratio ≥ 1.5 g/g; AND
       - **b)** Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for ≥ 90 days ([1] or [2]):
         - **(1)** Angiotensin converting enzyme inhibitor; OR
         - **(2)** Angiotensin receptor blocker; AND
     - **iv.** According to the prescriber, the patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
     - **v.** Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
     - **vi.** Patient has not previously been treated with Tarpeyo; AND
       Note: For a patient currently receiving Tarpeyo, review using Criterion 1B.
     - **vii.** The medication is prescribed by or on consultation with a nephrologist.
   - **B)** Patient is Currently Receiving Tarpeyo. Approve for up to 10 months (total) if the patient meets the following criteria (i, ii, iii, iv, v, and vi):
     Note: Approval is not to exceed 10 consecutive months; for example if a patient has received 3 consecutive months approve 7 months to complete 10 consecutive months of therapy.
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for ≥ 90 days (a or b):
       - **a)** Angiotensin converting enzyme inhibitor; OR
       - **b)** Angiotensin receptor blocker; AND

iv. According to the prescriber, the patient has received ≥ 90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
v. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
vi. The medication is prescribed by or on consultation with a nephrologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tarpeyo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tarpeyo™ capsules [prescribing information]. Stockholm, Sweden: Calliditas; December 2021.
2. Data on File. Phase 3 Part A Topline Data. Stockholm, Sweden: Calliditas; November 2020.
3. Data on File. Calliditas announces positive top-line results from pivotal Phase III NefigArd trial. Stockholm, Sweden: Calliditas; November 8, 2020.
4. KDIGO 2021 clinical practice guidelines for the management of glomerular diseases. *Kidney International.* 2021;100:S1-S276. Available at: https://www.kidney-international.org/action/showPdf?pii=S0085-2538%2821%2900562-7. Accessed on: December 20, 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/05/2022
Selected Revision	**Primary Immunoglobulin A Nephropathy:** The approval duration was changed to 10 months for initial therapy (previously the approval duration was 9 months) and up to 10 months for continuation therapy (previously the approval duration was up to 9 months).	01/19/2022