MEDICAL MUTUAL®

Drug Policy

Policy: SD	Tarpeyo (budesonide delayed-release)	Annual Review Date: 02/20/2024 Last Revised Date: 02/20/2024

OVERVIEW

Tarpeyo, a corticosteroid, is indicated to reduce proteinuria in adults with **primary immunoglobulin A nephropathy (IgAN)** at risk for disease progression.

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.

POLICY STATEMENT

This policy involves the use of Tarpeyo. Prior authorization is recommended for pharmacy benefit coverage of Tarpeyo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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, initial approval requires Tarpeyo be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. <u>Primary Immunoglobulin A Nephropathy (IgAN), initial therapy</u>
Criteria. *Patient must meet the following criteria*

- **A.** Patient is ≥ 18 years of age; AND
- **B.** The diagnosis has been confirmed by biopsy; AND
- **C.** Patient is at high risk of disease progression, defined by meeting the following criteria (a <u>and</u> b):
  - **a.** Patient meets ONE of the following:
    - **i.** Proteinuria > 0.75 g/day; OR
    - **ii.** Urine protein-to-creatinine ratio ≥ 0.8g/g; AND

b. Patient has been receiving the maximum or maximally tolerated dose of ONE of the following for ≥ 90 days:
  i. Angiotensin converting enzyme inhibitor (ACEi); or
  ii. Angiotensin receptor blocker (ARB); AND

D. 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
E. Patient has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2; AND
F. Patient has not previously been treated with Tarpeyo; AND
NOTE: for patients currently receiving Tarpeyo, review using Criterion 2
G. The medication is prescribed by or in consultation with a nephrologist

2. Primary Immunoglobulin A Nephropathy (IgAN), continuation of therapy
Criteria. *Patient must meet the following criteria*

A. Patient is ≥ 18 years of age; AND
B. The diagnosis has been confirmed by biopsy; AND
C. 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 (ACEi); OR
  b. Angiotensin receptor blocker (ARB); AND
D. 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
E. Patient has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2; AND
F. The medication is prescribed by or in consultation with a nephrologist

Initial Approval/ Extended Approval.
A) *Initial Approval:* 10 months
B) *Extended Approval:* up to 10 months total therapy duration
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

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tarpeyo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tarpeyo™ capsules [prescribing information]. Stockholm, Sweden: Calliditas; December 2023.
2. Barratt J, Lafayette R, Kristensen J, et al; for the NefIgArd Trial Investigators. Results from part A of the Multicenter, double-blind, randomized, placebo-controlled NefIgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy. *Kidney International.* 2022 Oct 19 [Epub ahead of print].
3. 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: January 10, 2023.
4. Lafayette R, Kristensen J, Stone A, et al; on behalf of the NefIgArd trial investigators. Efficacy and safety of a targeted-release formulation of budesonide in patients with primary IgA nephropathy (NefIgArd): 2-year results from a randomized phase 3 trial. *Lancet.* 2023;402(10405):859-870.