Effective date: 1/1/2023
Review date: 9/2022, 7/2023, 5/2024, 1/2025, 8/2025, 2/2026 Scope: Medicaid

TARPEYO (budesonide delayed release capsules)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

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

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

Primary immunoglobulin A nephropathy (IgAN)
Authorization of up to 10 months may be granted when all of the following criteria are met:
A. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A
B. nephropathy (IgAN).
C. The medication must be prescribed by or in consultation with a nephrologist.
D. Documentation with laboratory report and/or chart note(s) within the previous 3 months indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g based on a 24-hour urine collection.
E. Documentation that member's eGFR ≥35 mL/min/1.73 m^2
F. Member is receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin II receptor blockers [ARBs]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors.
G. Member has experienced a documented inadequate response from a 30-day trial, intolerance, or contraindication to an oral glucocorticoid (e.g. prednisone).
H. Member is not using medication in combination with Fabhalta, Vanrafia or Voyxact.
I. Member is not currently receiving dialysis or has undergone kidney transplant.

III. QUANTITY LIMIT

Tarpeyo 4mg capsule has a quantity limit of 4 capsules per day.

IV. REFERENCES

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; June 2024.
2. Fellstrom BC, Baratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomized, placebo-controlled phase 2b trial. Lancet. 2017 May 27;389 (10084): 2117-2127.

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3. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guidelines for the Management of Glomerular Disease. Kidney Int. 2021 Oct; 100 (4S): S1-S276. doi: 10.1016/j.kint.2021.05.021.
4. Clinical Consult. CVS Caremark Clinical Program Review: Focus on Nephrology Programs. February 10, 2022.