Effective date: 1/1/2023
Review date: 9/2022, 7/2023 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
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.

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

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN)
B. Laboratory report and/or chart note indicating that the member has proteinuria greater than or equal to 1 g/day or baseline UPCR greater than or equal to 1.5 g/g based on a 24-hour urine collection.

III. 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. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
B. 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]) or member has an intolerance or contraindication to RAS inhibitors.
C. Member has proteinuria greater than or equal to 1 g/day or UPCR greater than or equal to 1.5 g/g based on a 24-hour urine collection.
D. Member has experienced an intolerance to oral glucocorticoid (e.g., prednisone).

IV. QUANTITY LIMIT

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

V. REFERENCES

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; December 2021.
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.
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.