

## 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 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. 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 urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 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 0.8 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 2023.
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.