

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) 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. 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.
- F. Member is not using medication in combination with Fabhalta, Filspari or Vanrafia.
- 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 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.
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.