

Reference number(s) 5114-A

# Specialty Guideline Management Tarpeyo

## **Products Referenced by this Document**

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tarpeyo	budesonide

## **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 Indication<sup>1</sup>

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.

#### **Documentation**

Submission of the following information is necessary to initiate the prior authorization review:

- Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
- Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 gram per day (g/day) or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 grams per gram (g/g).

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# **Coverage Criteria**

## Primary Immunoglobulin A Nephropathy (IgAN)<sup>1-4</sup>

Authorization of up to 10 months may be granted when all of the following criteria are met:

- Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
- Member has either of the following:
  - Proteinuria greater than or equal to 1 g/day;
  - UPCR greater than or equal to 0.8 g/g
- Member is receiving a stable dose of maximally tolerated renin-angiotensin system (RAS)
  inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor
  blocker [ARB]) for at least 3 months of therapy, or member has an intolerance or
  contraindication to RAS inhibitors.

# **Continuation of Therapy**

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

#### 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. Barratt J, Lafayette R, Kristensen J, et al. Results from part A of the multi-center, double-blind, randomized, placebo-controlled NeflgArd trial, which evaluated targeted-release formulation of budesonide for the treatment of primary immunoglobulin A nephropathy [published online ahead of print, 2022 Oct 19]. Kidney Int. 2022;S0085-2538(22)00836-5. doi:10.1016/j.kint.2022.09.017.