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[1]

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).

Coverage Criteria

Primary Immunoglobulin A Nephropathy (IgAN)[1-4]

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 NefIgArd 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.