CVS Caremark®

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| 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 Indication1

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.