COMMON GROUND
HEALTHCARE COOPERATIVE

# PHARMACY POLICY STATEMENT
## Common Ground Healthcare Cooperative (CGHC)

| DRUG NAME | Tarpeyo (budesonide) |
|---|---|
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Tarpeyo is a novel formulation of the corticosteroid budesonide that was granted accelerated approval by the FDA in 2021 and converted to a traditional approval in 2023. It is indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
IgA nephropathy is the most common primary glomerular disease. It is an autoimmune condition caused by deposits of immunoglobulin A (IgA) in the kidney, leading to hematuria, proteinuria, and nephropathy (kidney disease) as the kidneys become unable to filter. This can slowly progress to end stage renal disease (ESRD) requiring dialysis or kidney transplant. ACE inhibitors or angiotensin receptor blockers (ARBs) are used to slow the progression of kidney disease, and immunosuppressive agents (i.e., steroids) may be added for those with rapidly progressing disease.
Tarpeyo was the first drug approved specifically for IgAN. As a delayed, sustained release formulation, Tarpeyo is released in a pulse-like manner only once it has reached the small intestine, allowing it to be delivered to the Peyer's patches in the ileum, which is theorized to be the source of IgA production. Being a targeted-release dosage form, Tarpeyo is subject to high first-pass metabolism resulting in lower systemic exposure and appears to elicit fewer and less severe systemic effects with better tolerability than high-dose systemic corticosteroids.

Tarpeyo (budesonide) will be considered for coverage when the following criteria are met:

### IgA Nephropathy (IgAN)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of primary IgA nephropathy confirmed by renal biopsy; AND
4. Chart notes indicate risk of disease progression per documentation of UPCR 1g/24 hr or greater; AND
5. Member has been stable on the max tolerated dose of an ACEi or ARB for at least 3 months; AND
6. Labs/chart notes must show an eGFR of 35 mL/min/1.73m$^2$ or greater; AND
7. Member has NOT had a kidney transplant.
8. **Dosage allowed/Quantity limit:** 16 mg (4 capsules) by mouth once daily for 9 months.
   When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy.
   QL: 120 capsules per 30 days

***If all the above requirements are met, the medication will be approved for 10 months.***

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For **reauthorization**:

1. Tarpeyo will not be reauthorized for continuous use.

## CareSource considers Tarpeyo (budesonide) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **01/27/2022** | New policy for Tarpeyo created. |
| **01/12/2024** | Updated references. Removed reauthorization note. Changed UPCR cutoff to match trial criteria instead of that stated in the original labeled indication. Removed “rapid” from risk of disease progression. Specified “primary” IgAN. |

References:


1. Tarpeyo [prescribing information]. Calliditas Therapeutics AB; 2023.
2. Fellström BC, Barratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomised, placebo-controlled phase 2b trial. *Lancet*. 2017;389(10084):2117-2127. doi:10.1016/S0140-6736(17)30550-0
3. 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. *Kidney Int*. 2023;103(2):391-402. doi:10.1016/j.kint.2022.09.017.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int*. 2021;100(4S):S1-S276. doi:10.1016/j.kint.2021.05.021


Effective date: 01/01/2025
Revised date: 01/12/2024