CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Tarpeyo (budesonide)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Tarpeyo is a novel formulation of the corticosteroid budesonide that was approved by the FDA in December 2021. It is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g.
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 are added for those with rapidly progressing disease. Tarpeyo is the first drug approved specifically for IgA nephropathy.
As a delayed, sustained release formulation, Tarpeyo is able to be released in a pulse-like manner only once it has reached the small intestine, allowing the drug 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 in this population.

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. Member has a diagnosis of IgA nephropathy confirmed by renal biopsy; AND
3. Member has a progressively declining glomerular filtration rate (GFR) and/or worsening proteinuria (e.g. UPCR 1.5 g/g or greater); AND
4. Member has been stable on the max tolerated dose of an ACEi or ARB for at least 3 months or has a contraindication to both; AND
5. Member has trialed one generic oral corticosteroid therapy.
6. **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.

For **reauthorization**:

1. Tarpeyo will not be reauthorized.

In part A of the NeflgArd clinical trial, the basis of accelerated FDA approval, the UPCR improvements continued through 12 months. The confirmatory part B of this study taking place over 2 years will evaluate long term benefit.

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.

References:

1. Tarpeyo [prescribing information]. Calliditas Therapeutics AB; 2021.
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. Efficacy and Safety of Nefecon in Patients With Primary IgA (Immunoglobulin A) Nephropathy (Nefigard). ClinicalTrials.gov Identifier: NCT03643965. Updated December 13, 2021. Accessed January 27,2022. https://clinicaltrials.gov/ct2/show/NCT03643965.
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

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Revised date: 01/27/2022