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Section:	Prescription Drugs	**Effective Date:**	October 24, 2025
Subsection:	Corticosteroids	**Original Policy Date:**	January 21, 2022
Subject:	Tarpeyo	**Page:**	1 of 4

Last Review Date: September 19, 2025

Tarpeyo

Description

Tarpeyo (budesonide) delayed-release capsules

Background
Tarpeyo (budesonide) is a corticosteroid with potent glucocorticoid activity and weak mineralocorticoid activity that undergoes substantial first pass metabolism. Mucosal B-cells present in the ileum, including the Peyer's patches, express glucocorticoid receptors and are responsible for the production of galactose-deficient IgA1 antibodies (Gd-Ag1) causing IgA nephropathy. Through their anti-inflammatory and immunosuppressive effects at the glucocorticoid receptor, corticosteroids can modulate B-cell numbers and activity (1).

Regulatory Status
FDA-approved indication: Tarpeyo is a corticosteroid indicated to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression (1).

The recommended duration of therapy is 9 months, with a dosage of 16 mg administered orally once daily. When discontinuing therapy, reduce the dosage to 8 mg once daily for the last 2 weeks of therapy. Safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established (1).

Tarpeyo contains warnings regarding hypercorticism and adrenal axis suppression, risks of immunosuppression, and other corticosteroid effects (1).

The clinical trials for Tarpeyo had inclusion criteria for patients to be on a maximum recommended or maximum tolerated dose of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB). Patients also had an estimated glomerular filtration rate (eGFR) of ≥ 35 mL/min/1.73 m2. The trial also had exclusion criteria for patients who had undergone a kidney transplant; patients with severe liver disease; patients with type 1 or type 2 diabetes mellitus; and patients with uncontrolled cardiovascular disease (2).

The safety and efficacy of Tarpeyo in pediatric patients less than 18 years of age have not been established (1).

Related policies
Filspari

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tarpeyo may be considered **medically necessary** if the conditions indicated below are met.

Tarpeyo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

a. Diagnosis has been confirmed by a kidney biopsy
b. Patient is at risk for disease progression indicated by proteinuria ≥ 1.0 g/day
c. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy
d. Prescribed by or recommended by a nephrologist

e. Patient has **NOT** had a kidney transplant
f. **NO** severe hepatic impairment (Child-Pugh Class C)

Prior – Approval *Renewal* Requirements

None

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 4 capsules per day / 1,108 capsules (quantity sufficient for 9 months plus a 2 week taper)

Duration* 12 months

*PA duration is set for 12 months to allow time to fill despite the quantity being for one treatment course of 9 months.

Prior – Approval *Renewal* Limits

None

Rationale

Summary

Tarpeyo (budesonide) is a corticosteroid used to treat adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. The recommended treatment duration is one treatment course of 9 months. Tarpeyo contains warnings regarding hypercorticism and adrenal axis suppression, risks of immunosuppression, and other corticosteroid effects. The safety and efficacy of Tarpeyo in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tarpeyo while maintaining optimal therapeutic outcomes.

References

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; June 2024.
2. Fellstrom 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. May 27, 2017;389(10084):2117-2127.

Policy History

Date	Action
January 2022	Addition to PA
March 2022	Annual review
April 2022	Changed PA duration from 9 months to 12 months to allow time for patient to fill. Addition of requirements per FEP: used with ACEI/ARB therapy, no kidney transplant, eGFR ≥ 35, no diabetes or uncontrolled cardiovascular disease, no severe hepatic impairment
June 2022	Annual review
September 2022	Per FEP, adjusted PA quantity to 1108 capsules to allow for 9 months treatment plus a 2 week taper; 28 capsules added to account for taper
December 2022	Annual review
June 2023	Annual review
June 2024	Annual editorial review and reference update. Changed FDA approved indication. Per FEP, retained UPCR requirement
June 2025	Annual review and reference update
August 2025	Per FEP, replaced UPCR with proteinuria in requirements
September 2025	Annual review
October 2025	Per reconsideration review, removed eGFR requirement and removed exclusion of diabetes mellitus or uncontrolled cardiovascular disease

Keywords

This policy was effective with interim approval on October 24, 2025 and will be reviewed by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025.