

5.22.002

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2023
<b>Subsection:</b>	Corticosteroids	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Tarpeyo	<b>Page:</b>	1 of 4

---

**Last Review Date:** June 15, 2023

---

## 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 proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g (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).

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2023
<b>Subsection:</b>	Corticosteroids	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Tarpeyo	<b>Page:</b>	2 of 4

---

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  $\geq 35$  mL/min/1.73 m<sup>2</sup>. 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

### 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:

- Diagnosis has been confirmed by a kidney biopsy
- Patient is at risk of rapid disease progression indicated by a urine-to-creatinine ratio (UPCR)  $\geq 1.5$  g/g
- Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy
- Prescribed by or recommended by a nephrologist
- Patient has **NOT** had a kidney transplant

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2023
<b>Subsection:</b>	Corticosteroids	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Tarpeyo	<b>Page:</b>	3 of 4

---

- f. eGFR  $\geq$  35 mL/min/1.73 m<sup>2</sup>
- g. **NO** diabetes mellitus or uncontrolled cardiovascular disease
- h. **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 of rapid 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.

---

<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	July 1, 2023
<b>Subsection:</b>	Corticosteroids	<b>Original Policy Date:</b>	January 21, 2022
<b>Subject:</b>	Tarpeyo	<b>Page:</b>	4 of 4

---

## References

1. Tarpeyo [package insert]. Stockholm, Sweden: Calliditas Therapeutics AB; December 2021.
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 $\geq$ 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

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.**