

## SAMPLE Letter of Medical Necessity for Appeal and/or Medical Exception

To be written on HCP office or provider letterhead

<Today's date>

<Insurance Company>

<Address>

Re: <If applicable: PA denial reference # & date>

<Patient name>

<DOB>

<Policy number>

To whom it may concern:

I am writing on behalf of <patient name> to document the medical necessity of TARPEYO® (budesonide) delayed release capsules. 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.

### 1. Diagnosis

<Example: The patient was diagnosed on <date>, via kidney biopsy, with primary immunoglobulin A nephropathy (IgAN)...>

### 2. IgAN medication history

Current therapy	Dose
<Example: ACEs/ARBs>	

Previous therapy	Reason for discontinuation
<Example: Glucocorticoids>	<Example: intolerance, inadequate response>

### 3. Laboratory results

<Example: Relevant laboratory results:>

- Most recent UPCR and eGFR>

### 4. Rationale for treatment

<Example: Considering <patient name> is at high risk of chronic kidney disease (CKD) progression despite supportive care, which includes maximally tolerated angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs), blood pressure management, and lifestyle modification per KDIGO 2021 practice guideline, it is my medical opinion that treatment with TARPEYO is medically appropriate and necessary.>

<If payer denied TARPEYO and required generic or other formulations of budesonide, include additional supporting statements.>

Example: TARPEYO is not interchangeable with other formulations of budesonide. Other formulations of budesonide have not been studied, FDA approved, nor compendia listed for IgAN.>

[NOTE: Exercise your medical judgment and discretion when characterizing the patient's medical condition.]

Please contact my office by calling <insert phone number> for any additional information you may require in support of this appeal. I look forward to your timely approval.

Sincerely,

<Physician name and signature>

<Name of practice>

<Phone #>

*This sample Letter of Medical Necessity is provided for informational purposes and is not intended to substitute for a prescriber's independent medical decision-making. Use of this sample letter does not guarantee the health plan will approve TARPEYO for your patient.*

**The Important Safety Information below is intended for communication to HCPs but does not need to be included in the letter to the Payors.**

## **Indication**

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.

## **Important Safety Information**

**Contraindications:** TARPEYO is contraindicated in patients with hypersensitivity to budesonide or any of the ingredients of TARPEYO. Serious hypersensitivity reactions, including anaphylaxis, have occurred with other budesonide formulations.

## **Warnings and Precautions**

**Hypercorticism and adrenal axis suppression:** When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. Corticosteroids can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to surgery or other stress situations, supplementation with a systemic corticosteroid is recommended. When discontinuing therapy or switching between corticosteroids, monitor for signs of adrenal axis suppression.

Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C respectively) could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure to oral budesonide. Avoid use in patients with severe hepatic impairment (Child-Pugh Class C). Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

**Risks of immunosuppression:** Patients who are on drugs that suppress the immune system are more susceptible to infection than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in susceptible patients or patients on immunosuppressive doses of corticosteroids. Avoid corticosteroid therapy in patients with active or quiescent tuberculosis infection, untreated fungal, bacterial, systemic viral, or parasitic infections, or ocular herpes simplex. Avoid exposure to active, easily-transmitted infections (e.g., chicken pox, measles). Corticosteroid therapy may decrease the immune response to some vaccines.

**Other corticosteroid effects:** TARPEYO is a systemically available corticosteroid and is expected to cause related adverse reactions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, or with a family history of diabetes or glaucoma, or with any other condition where corticosteroids may have unwanted effects.

**Adverse reactions:** In clinical studies, the most common adverse reactions with TARPEYO (occurring in  $\geq 5\%$  of TARPEYO treated patients, and  $\geq 2\%$  higher than placebo) were peripheral edema (17%), hypertension (12%), muscle spasms (12%), acne (11%), headache (10%), upper respiratory tract infection (8%), face edema (8%), weight increased (7%), dyspepsia (7%), dermatitis (6%), arthralgia (6%), and white blood cell count increased (6%).

**Drug interactions:** Budesonide is a substrate for CYP3A4. Avoid use with potent CYP3A4 inhibitors, such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, and cyclosporine. Avoid ingestion of grapefruit juice with TARPEYO. Intake of grapefruit juice, which inhibits CYP3A4 activity, can increase the systemic exposure to budesonide.

## **Use in specific populations**

**Pregnancy:** The available data from published case series, epidemiological studies, and reviews with oral budesonide use in pregnant women have not identified a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are risks to the mother and fetus associated with IgAN. Infants exposed to in-utero corticosteroids, including budesonide, are at risk for hypoadrenalism.

**Please see Full Prescribing Information for TARPEYO.**