



1-833-444-8277 • Fax: 1-844-854-3251 • 8 am to 8 pm ET Monday-Friday

1 PATIENT INFORMATION

*Cannot initiate enrollment without this completed.

*Patient First Name		*Patient Last Name		*Date of Birth (MM/DD/YY) / /	
*Street Address			Apt #	*Birth Sex <input type="checkbox"/> Male <input type="checkbox"/> Female	
*City	*State	*ZIP	Preferred Language <input type="checkbox"/> English <input type="checkbox"/> Other:		
*Preferred Phone #		Email			
Alternate Contact or Authorized Caregiver Name (if applicable)			Relationship to Patient (if applicable)		
Alt. Contact Phone # (if applicable)					

2 PATIENT INSURANCE

*Do you have insurance coverage? Yes No If Yes: I have included a copy of the front and back of my medical and prescription benefit insurance cards.

INSURANCE	PHONE #	POLICY ID #	GROUP #	BIN	PCN	POLICYHOLDER NAME / DATE OF BIRTH
Prescription Benefit Insurance Name						Name
						Date of Birth

3 DIAGNOSIS

*Select an appropriate diagnosis code:

<input type="checkbox"/> N02.B1 Recurrent and persistent IgAN with glomerular lesion	<input type="checkbox"/> N02.B2 Recurrent and persistent IgAN with focal and segmental glomerular lesion
<input type="checkbox"/> N02.B3 Recurrent and persistent IgAN with diffuse membranoproliferative glomerulonephritis	<input type="checkbox"/> N02.B4 Recurrent and persistent IgAN with diffuse membranous glomerulonephritis
<input type="checkbox"/> N02.B5 Recurrent and persistent IgAN with diffuse mesangial proliferative glomerulonephritis	<input type="checkbox"/> N02.B6 Recurrent and persistent IgAN with diffuse mesangiocapillary glomerulonephritis
<input type="checkbox"/> N02.B9 Other recurrent and persistent IgAN	<input type="checkbox"/> Other: _____

4 PRESCRIBER INFORMATION

*Prescriber First Name		*Prescriber Last Name		*MD NPI #	
*Organization Name					
*Street Address			Suite #	State License #	
*City		*State		*ZIP	
*Organization Phone #			*Organization Fax #		
*Organization Contact Name			Organization Contact Email		
*Organization Contact Phone #			Preferred Method of Contact: <input type="checkbox"/> Email <input type="checkbox"/> Phone <input type="checkbox"/> Fax		

5 *PRESCRIPTION

TARPEYO is distributed exclusively through PANTHERx Rare Pharmacy. Please select PANTHERx Specialty Pharmacy if ePrescribing or check this box which serves as a 9 month and 2-week taper prescription for your patient. For alternate dosing, please ePrescribe or contact TARPEYO Touchpoints to provide the prescription.

- | | | |
|--------------------------------------------------------------------------------------------------------------------------------------|------|-----------|
| <input type="checkbox"/> TARPEYO® (budesonide) delayed release capsules, 4 mg—Take 4 capsules PO QD x 30 days for the first 9 months | #120 | 8 refills |
| Taper Prescription: TARPEYO® (budesonide) delayed release capsules, 4 mg—Take 2 capsules PO QD x 14 days | #28 | 0 refills |

BRIDGE PRESCRIPTION INFORMATION

Complete this optional, additional prescription to receive a limited supply of TARPEYO at no cost for eligible patients who experience a delay in insurance coverage.

- | | | |
|---------------------------------------------------------------------------------------------------------------|-----|-----------|
| <input type="checkbox"/> TARPEYO® (budesonide) delayed release capsules, 4 mg—Take 4 capsules PO QD x 15 days | #60 | 3 refills |
|---------------------------------------------------------------------------------------------------------------|-----|-----------|

*Prescriber Signature (no stamps)

Date (MM/DD/YYYY)

By submitting this form, the Prescriber and Office certify the following statements: (i) The information provided in this form is current, accurate, and complete. (ii) TARPEYO® (the Product) has been determined by the Prescriber to be medically necessary for the patient, the patient is prescribed the Product for an FDA-approved indication, and the patient meets the eligibility requirements for the Tarpeyo Touchpoints Programs selected (the Program). (iii) Prescriber and Office have the necessary authorization and consents on file to share personal information with third party service providers (Agents) of Calliditas Therapeutics US Inc. (Calliditas) in connection with their treatment. (iv) Prescriber and the Office will not submit or cause submission of any claims for payment or reimbursement in connection with the Program to third-party insurers including without limitation Medicare or Medicaid. (v) Prescriber and Office are under no obligation to prescribe the Product or participate in the Program. (vi) Prescriber and Office have not and will not receive any benefit from Calliditas for prescribing any Calliditas products. (vii) Calliditas may suspend Prescriber and/or Office's participation in the Program at any time. (viii) Prescriber and Office understand that Calliditas and its Agents are relying upon the accuracy and completeness of this certification.



PATIENT CONSENT AND PRIVACY NOTICE

(You are not required to sign this form to receive treatment. Your signature on this form is only required to receive patient support services from TARPEYO Touchpoints®.)

Patient will receive a call about accessing TARPEYO from 1-833-444-8277

1. **Signatures.** Your signature will be valid for a period of 3 years unless a shorter period is required by law. Federally insured patients will be re-enrolled every year (Medicare). **If you are completing this form on behalf of a patient,** you certify that you are the parent, legal guardian, healthcare power of attorney, or authorized representative of the patient. References to “you” or “your” below refer to the patient. By signing this document (the Authorization), you certify that you have read, understood, and agree to: (i) the terms and conditions of Tarpeyo Touchpoints® (the Program), (ii) your obligations below, and (iii) the collection and use of your personal information (including income verification) by Calliditas Therapeutics US Inc. including its affiliates (collectively, Calliditas) and its third-party service providers (Agents).
2. **Eligibility.** You understand your enrollment in the Program is not guaranteed. Calliditas may modify or revoke the Program at any time. Your participation in the Program and related services for Tarpeyo (the Product) is subject to the following criteria:
 - a. **General Criteria:** (i) You have kidney biopsy confirmed primary immunoglobulin A nephropathy (IgAN), (ii) you are age 18 or older, (iii) you have a valid prescription for the Product from your healthcare provider, and (iv) you are a resident of the U.S. or its territories.
 - b. **Bridge:** (i) You meet General Criteria; (ii) you have commercial insurance and an authorization or appeal of coverage denial has been submitted to your insurance plan.
 - c. **PAP:** (i) You meet General Criteria, (ii) you are uninsured or under-insured for the Product, and (iii) you meet financial eligibility criteria. Program provides Tarpeyo for free to eligible patients for up to 9.5 months, or until they receive coverage approval, whichever occurs earlier.
 - d. **Co-pay Card:** (i) you are a resident of the U.S. or its territories, and; (ii) you have commercial insurance including prescription drug coverage for the Product. The Co-pay Card is not valid if you choose cash payment for the Product.
3. **Income Verification.** Calliditas’ Agents will conduct electronic income verification using third party consumer credit reporting agencies (e.g., Experian). If electronic verification cannot be done, you will be asked for verifiable documentation of your household income. Your household is limited to you, your spouse, and your dependents. Income verification will happen annually.
4. **Personal Information.**
 - a. Calliditas is committed to your privacy and will use appropriate measures to protect your personal information (Your Information). **Your Information includes your name, gender, date of birth, address, contact information, insurance or pharmacy benefits, diagnosis, treatment, and prescriptions.** Neither Calliditas nor its Agents will sell Your Information or share it with third parties other than Calliditas’ Agents. Calliditas compensates its Agents for their services, not for Your Information.
 - b. You authorize your health care providers, insurers, and their contractors (collectively, Your Providers) to disclose Your Information to Calliditas or its Agents. Calliditas or its Agents may also collect Your Information directly from you or consumer credit reporting agencies. Your Information is necessary and will be used by Calliditas or its Agents to: (i) determine your eligibility and enroll you in the Program, (ii) operate and administer the Program to provide you with appropriate services, (iii) communicate with Your Providers about your treatments, (iv) have the Product delivered to you, (v) contact you regarding the Program, your services, and to obtain further information or clarification of any adverse events you experience with the Product, (vi) perform research and analytics to develop and/or evaluate Calliditas’ products, services, materials, treatments, and the Program. Telephone calls may be recorded for quality and other legitimate purposes, (vii) address and improve insurance coverage for the Product. Once Your Information has been disclosed to Calliditas, federal privacy laws may no longer protect Your Information from further disclosure. However, Calliditas will use Your Information only according to this Authorization.
 - c. Calliditas and its Agents may receive both Identifiable and De-identified versions of Your Information. “Identifiable” means Your Information can readily identify you as an individual (e.g. your name). “De-identified” means enough information has been redacted, replaced, or obscured so that it cannot reasonably identify you. Calliditas and its Agents may use Identifiable information only for the purposes described by this Authorization. Calliditas and its Agents may use De-identified information for any legitimate and lawful purpose.
 - d. You have certain legal rights regarding Your Information according to the privacy laws where you live, such as the right to access or correct Your Information. You understand that you may refuse to sign this Authorization and that a refusal to will not negatively affect your ability to enroll in the Program or obtain services from Calliditas in the future.
 - e. You understand you may revoke your Authorization. **However, revoking your Authorization means you will no longer be able to participate in the Program or continue receiving related services.** Withdrawal of your Authorization will not invalidate Your Providers’, Calliditas’ or its Agents’ collection, use or disclosure of Your Information before written notice is received and processed. You understand you may send questions or requests regarding your Authorization and Your Information in writing to PANTHERx Rare Pharmacy, ATTN: TARPEYO Touchpoints, 121 Bayer Road, Building 5, Pittsburgh, PA 15205.
5. **Your Obligations.** You certify that your application is complete and accurate. You will promptly notify Calliditas’ Agent at tarpeyotouchpoints@pantherxrare.com regarding changes to Your Information (e.g., changes to your household income, address, or contact information). Failure to promptly update Your Information may delay communications about the Program or receipt of the Product. Failure to provide Your Information may affect your eligibility for the Program or certain services. You will promptly notify the Agent if you obtain insurance coverage for the Products provided through the Program or no longer meet the financial eligibility criteria for services you receive. If you are commercially or federally insured, (i) you will not submit or cause others to submit any claim to a commercial insurer, federal insurer, or pharmacy benefit plan for any free Product you receive, (ii) if you have Medicare Part D coverage, you will not have the cost/value of the free Product counted as out-of-pocket costs, and (iii) you will inform your plan about your enrollment in the Program as necessary. You will not sell, trade, or transfer any Product. You are responsible for your own messaging or data rates.
6. **SELECT ADDITIONAL OPT IN FOR OTHER RESOURCES (check all that apply).** You may opt-in to one or more of the following at your discretion. Choosing not to opt-in to one or more of the following will not negatively affect your ability to receive the Product, enroll in the Program, or receive related services. Communications and information may be provided by Calliditas or its Agents.
 - TEXT MESSAGES:** You wish to receive text messages (where available) for communication about your enrollment, insurance coverage, the Program, and the services you receive. By checking this box, you will receive general communications regarding your participation in the Program. If you check this box and one or more of the following, you may receive text messages about what you’ve opted-in to receive. Message and data rates may apply.
 - PATIENT RESOURCES:** You wish to receive patient resources such as information about your disease or medication adherence reminders
 - MARKETING COMMUNICATIONS:** You authorize Your Providers to share Your Information with Calliditas or its Agents for marketing purposes. You wish to receive marketing communications regarding Calliditas or its other products and services.
 - RESEARCH STUDIES:** You wish to receive information about research studies sponsored by Calliditas such as market research, patient registries, clinical trials, or other studies.



I have read and agree to the Patient Consent and Privacy Notice:

*Patient’s or Patient Representative’s Name (Print)

*Patient’s or Patient Representative’s Signature

*Date (MM/DD/YYYY)



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).

Immunosuppression and Increased Risk of Infection: Corticosteroids, including TARPEYO, suppress the immune system and increase the risk of infection with any pathogen, including viral, bacterial, fungal, protozoan, or helminthic pathogens. Corticosteroids can: reduce resistance to new infections, exacerbate existing infections, increase the risk of disseminated infections, increase the risk of reactivation or exacerbation of latent infections, and mask some signs of infection. Corticosteroid–associated infections can sometimes be serious. Monitor for infection and consider TARPEYO withdrawal as needed.

Avoid corticosteroid therapy, including TARPEYO, in patients with active or quiescent tuberculosis or hepatitis B infection; untreated fungal, bacterial, systemic viral, or parasitic infections; ocular herpes simplex; or Kaposi's sarcoma. Avoid exposure to active, easily–transmitted infections (e.g., chickenpox, 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 accompanying Full Prescribing Information.