TARPEYO® (budesonide) delayed release capsules • 4 mg | Touchpoints™ Support beyond the script

Enrollment Form

About TARPEYO Touchpoints™

TARPEYO Touchpoints offers services, assistance, and resources to help patients access TARPEYO® (budesonide) delayed release capsules as easily as possible. TARPEYO Touchpoints provides a wide range of support that covers access, financial assistance, ordering and delivery, and treatment adherence.

How to enroll in TARPEYO Touchpoints

- ☐ Before you begin, have the following information ready:
  - Patient information, including prescription benefit insurance information (and medical and secondary benefit insurance if applicable)
  - Supporting clinical information, including recent proteinuria/UPCR and eGFR values, kidney biopsy documentation, and current and past medications list
- ☐ Fill out all required fields in the enrollment form. Required fields are indicated by a red asterisk (*).
- ☐ Make sure both patient and prescriber sign and date this form. The form cannot be processed without signatures from both.
- ☐ Fax completed form and supporting clinical information to **1-844-854-3251**.

What to expect after program enrollment

- Patient and prescriber will receive a call from a TARPEYO Touchpoints Care Navigator to follow up on any missing information, if needed, and to welcome the patient to TARPEYO Touchpoints
- Remind the patient it's important to pick up calls from 1-833-444-8277

How to reach us if you have questions

1-833-444-8277

TARPEYO Touchpoints™ Enrollment Form

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1-833-444-8277 • Program fax: **1-844-854-3251** • Hours of operation: **8 AM to 8 PM ET** • **TarpeyoTouchpoints.com**

1 PATIENT INFORMATION

*Cannot initiate enrollment without this completed.

*Patient First Name	*Patient Last Name		*Date of Birth (MM/DD/YY) / /
*Street Address		Apt #	*Gender ☐ Male ☐ Female
*City	*State	*ZIP	*US Resident ☐ Yes ☐ No
*Preferred Phone #	Alternate Phone #	Email	
Preferred Time of Day to Contact ☐ Morning ☐ Afternoon ☐ Evening ☐ OK to leave message		Preferred Language ☐ English ☐ Other:	
*Alternate Contact or Authorized Caregiver Name (if applicable)		*Relationship to Patient (if applicable)	
*Alt. Contact Phone # (if applicable)	Alt. Contact Email (if applicable)		

Patient authorization:

*Patient Signature ______________________ *Date (MM/DD/YYYY) / /

☐ *I have read and agree to the Patient Authorization to Share Health Information on page 3.

☐ *I have read and agree to the Financial Eligibility for Patient Assistance Program on page 3.

☐ I consent to receiving other resources related to my medicine or IgA nephropathy using my information provided on this form (optional). Please see Opt-in Terms on page 3.

2 PATIENT INSURANCE & FINANCIAL INFORMATION

***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

If you do not have insurance coverage and would like to apply for the TARPEYO Touchpoints™ Patient Assistance Program, please complete the financial information below.

FINANCIAL INFORMATION	Annual Gross Household Income	Number of Household Members (Including Patient)

3 CLINICAL INFORMATION

*Primary Diagnosis ICD-10	Description
*Has the patient had a kidney biopsy–confirmed diagnosis of IgA nephropathy? ☐ Yes ☐ No	
☐ I have included clinical notes with the enrollment form, including current and previous medications list, and kidney biopsy documentation.	

4 PRESCRIBER INFORMATION

*Prescriber First Name	*Prescriber Last Name		*MD NPI #
*Practice Name			Tax ID #
*Street Address		Suite #	State License #
*City	*State	*ZIP	
*Office Phone #	*Office Fax #	Email	
*Office Contact		Office Contact Title	
Preferred Time of Day to Contact ☐ Morning ☐ Afternoon ☐ Evening		Preferred Communication Method ☐ Phone ☐ Email ☐ Fax	
*Office Contact Phone #		Office Contact Email	

5 *PRESCRIPTION INFORMATION

☐ TARPEYO® (budesonide) 4 mg delayed release capsules—Take 4 capsules PO QD x 30 days #120 9 refills			
☐ TARPEYO® (budesonide) 4 mg delayed release capsules	Directions	Quantity	Refills Authorized

6 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.

☐ TARPEYO® (budesonide) 4 mg delayed release capsules—Take 4 capsules PO QD x 15 days #60 3 refills

Prescriber authorization

I certify that the above therapy is medically necessary, and that this information is accurate to the best of my knowledge. I certify that I am the physician who has prescribed TARPEYO to the previously identified patient above, and that I provided the patient with a description of the TARPEYO Touchpoints program. For the purpose of transmitting these prescriptions, I authorize TARPEYO Touchpoints, and its affiliates, to forward as my agent for the limited purposes these prescriptions electronically, by facsimile, or by mail to Biologics specialty pharmacy.

*Prescriber Signature (no stamps) ______________________ *Date (MM/DD/YYYY) / /

Please see Important Safety Information on page 4 and the accompanying Full Prescribing Information.
Please read the following pages carefully, then sign and date where indicated in section 1 on this page.

PATIENT AUTHORIZATION TO SHARE HEALTH INFORMATION:

By signing this Authorization to Share Health Information ("Authorization"), I authorize my health care providers (including my pharmacies and my doctors), my health insurers, and their contractors (collectively, the "Parties") to disclose to Calliditas Therapeutics US Inc., its parent and affiliates, and its third-party business partners, vendors, and other agents ("Agents") (together with Calliditas Therapeutics US and its parent and affiliates, "Calliditas") information about my illnesses and health conditions, my medical treatments, my medicines, my medical test results, and my health insurance coverage ("my Information") for the purposes described in this form.

- ***Permitted Purposes:*** By signing on page 2, I authorize the Parties and Calliditas (including its Agents) to use and disclose my Information for the purposes of providing certain support services, including, but not limited to: **(1)** determining if I am eligible to participate in the TARPEYO Touchpoints™ patient support program ("the Program"); **(2)** managing and improving the Program; **(3)** communicating with me about my experience with the Program; **(4)** sending me materials relating to the Program; **(5)** investigating my health insurance coverage; **(6)** seeking health insurance coverage for TARPEYO®, including assistance with obtaining prior authorization for TARPEYO; **(7)** operating and administering the Program; and **(8)** contacting me for follow-up on any adverse event I may report regarding a Calliditas product.
- ***De-identification:*** I further authorize Calliditas to have my health information de-identified and use it in performing research, education, business analytics, and marketing studies, or for other commercial purposes, including linkage with other de-identified information Calliditas may receive from other sources.
- **Redisclosure:** I understand that once my Information has been disclosed to Calliditas, federal privacy laws may no longer protect the Information from further disclosure, but that Calliditas intends to use and disclose my Information only in accordance with this Authorization or as otherwise allowed by law.
- ***Payment to pharmacies:*** I understand that Calliditas may provide my pharmacy with payment in order to obtain my Information.
- ***Right to refuse:*** I understand that I may refuse to sign this Authorization and that a refusal to sign will not affect my ability to obtain medical care, health insurance coverage, or eligibility for benefits. However, if I do not sign this Authorization, Calliditas cannot provide me with support services.
- ***Expiration:*** I understand that this Authorization expires two (2) years from the date I signed unless applicable law requires an earlier expiration or unless or until I withdraw (take back) this Authorization before then.
- ***Withdrawal:*** I understand that I may withdraw this Authorization at any time by sending a written notice that includes my name, address, and phone number, to Calliditas, ATTN: Tarpeyo Touchpoints, 11800 Weston Parkway, Cary, NC 27513. Withdrawal of this Authorization will end further reliance on this Authorization (and my participation in the Program) but it will not invalidate reliance on the Authorization to use or disclose my Information before my notice of withdrawal is received and processed.

By signing on page 2, I certify that I have read and understand the Authorization to Release Personal Health Information and agree to its terms. I understand that I am entitled to a copy of this Authorization upon request.

OPT-IN TERMS FOR OTHER RESOURCES

By checking the box on page 2, I authorize Calliditas Therapeutics to contact me by mail, email, and/or telephone regarding other potential topics of interest to me including disease state and products, promotions, services, and research studies. I understand that I am not required to provide this consent as a condition of receiving any Calliditas medicine or Patient Support Services.

FINANCIAL ELIGIBILITY FOR PATIENT ASSISTANCE PROGRAM

I understand that I have the option to consent to having Calliditas perform an electronic verification of my financial information to verify my eligibility and process my application for the TARPEYO Touchpoints Patient Assistance Program ("PAP"). By signing the Patient Authorization, I understand I am providing "written instructions" under the Fair Credit Reporting Act ("FCRA") authorizing Calliditas to obtain information from my credit profile, solely for the purpose of determining financial qualifications for PAP. I understand this authorization allows Calliditas to perform this process as needed for the duration of my participation in PAP.

I certify that the financial and health plan information I have provided is complete and accurate to the best of my knowledge. I understand that the TARPEYO Touchpoints PAP includes eligibility criteria, including demonstration of financial need, and that Calliditas will make an assessment about whether I meet those criteria. If I receive free product through PAP, I will not submit, or cause to be submitted any claims for payment or reimbursement from any third-party payer, including any federal healthcare program such as Medicare or Medicaid, or any private or other insurance plan, or from any other person or entity for such free product. The cost of any product provided under PAP will not count toward any Medicare true out-of-pocket costs. I agree to notify Calliditas promptly if: (1) I obtain coverage for products provided under PAP through another source (federal, state, or private health plan), or (2) I no longer meet the income criteria for PAP. If required by my health plan, I will notify the health plan of any free product I receive through PAP. I agree to notify my Medicare plan that I will receive my medication for free until the end of the calendar year through PAP. I understand that I must reapply for PAP annually. I also understand that Calliditas has the right at any time, and without notice to modify or discontinue free product that it may be providing under PAP.

Indication

TARPEYO® (budesonide) delayed release capsules 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) ≥1.5 g/g.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether TARPEYO slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

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 *[see Dosing and Administration]* 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. Chicken pox 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 (eg, 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, cataracts, a family history of diabetes or glaucoma, or with any other condition in which corticosteroids may have unwanted effects.

Adverse reactions: In clinical studies, the most common adverse reactions with TARPEYO (occurring in ≥5% of TARPEYO patients and ≥2% higher than placebo) were hypertension (16%), peripheral edema (14%), muscle spasms (13%), acne (11%), dermatitis (7%), weight increase (7%), dyspnea (6%), face edema (6%), dyspepsia (5%), fatigue (5%), and hirsutism (5%).

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.

calliditas THERAPEUTICS

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