CALA TAPS THERAPY: STANDARD WRITTEN ORDER—PRESCRIPTION FORM—LETTER OF MEDICAL NECESSITY

Cala Healthcare Professional Line: 1-888-585-7101	Submit completed forms via:
Cala Customer Care: 1-888-699-1009	Fax: 1-833-230-9251
Encrypted Email: Intake@CalaHealth.com	Secure Upload: CalaRx.com

PATIENT INFORMATION

First Name:	Last Name:	
Date of Birth:	Gender: ☐ Male ☐ Female	
Address:	Email:	
City:	State:	Zip:
Primary Phone:	Home Phone:	

PRESCRIPTION DETAILS (SELECT FROM EACH COLUMN)

Wrist Measurement*	Tremor Task**	Hand	Cala Stimulator (K1018)	Cala Bands (K1019)	Length of prescription
_____ centimeters	☐ Outstretched ☐ Wing Beating	☐ Left ☐ Right	1	4 - Each band is a three-month supply = 3 monthly units	☐ Lifetime (99) _____ Duration in Months
		☐ Both	2	8 - Each band is a three-month supply = 3 monthly units	

* Please provide a measurement of the patient's wrist in centimeters. Measure the patient's wrist circumference proximal to the head of the ulna.

** The Tremor Task is a postural hold that helps characterize the patient's tremor. Most patients use the outstretched postural hold. Please note if the patient should use the alternative postural wing beating hold.

LETTER OF MEDICAL NECESSITY

Diagnosis ICD-10 Code (required):

☐ **G25.000 Essential tremor** ☐ **Other** _____

☐ Confirmation: Patient does not have any of these contraindications:
- An implanted electrical medical device, such as a pacemaker, defibrillator, heart monitor, insulin pump, bladder stimulator, or deep brain stimulator
- Suspected or diagnosed epilepsy or other seizure disorder
- Pregnancy

☐ Confirmation: Patient tremor is not caused by:
- Medication-induced tremor
- Thyroid issues (e.g., hyperthyroidism)
- Metabolic disorders (e.g., B-12 deficiency)

Unique Patient Characteristics (check all that apply)

☐ Negative impacts to quality of life
☐ Forced to change jobs/retire/end employment
☐ Depression
☐ Anxiety/Stress
☐ Medications causing side effects
☐ Tremor responds to alcohol
☐ Not a candidate for deep brain stimulation or focused ultrasound
☐ Additional comments (attach if needed) _____
_____

Clinical Findings (check all that apply)

☐ Family History of tremor
☐ Uncontrolled shaking
☐ Tremors on action or intention
☐ Difficulty holding items
☐ Frequently spills/drops items
☐ Difficulty eating normally
☐ Difficulty with dressing/daily hygiene needs
☐ Difficulty writing legibly/signature
☐ Difficulty using cell phone/computers

Reasons Cala TAPS Therapy is Required (check all that apply)

☐ Ability to improve daily function for independent self-care
☐ Patient has failed to improve with usage of traditional treatment options
☐ Shared Decision patient wants to try non-pharmacological therapy, non-invasive treatment

Previous Pharmacological Treatments (check all that apply)

☐ Primidone
☐ Propranolol
☐ Other _____
☐ Contraindicated to pharmacology

PRESCRIBER AUTHORIZATION

This document serves as a Standard Written Order, Prescription, and Letter of Medical Necessity for Cala TAPS Therapy for this patient. As this patient's physician, I attest that the clinical findings on this document accurately reflect the health information. I certify that the Cala TAPS Therapy is reasonable and medically necessary for the treatment of this patient.

Prescriber's Signature:		Date:
First Name:	Last Name:	
NPI:	HCP: ☐ MD/DO or ☐ CRNP/PA	
Practice Name/Institution:		Tax Id:
Practice Contact Name:	Practice Contact Phone:	
Practice Contact Email:		
Address:	Practice Fax:	
City:	State:	Zip:

Transcutaneous Afferent Patterned Stimulation (TAPS)
Medical Evaluation and Documentation Considerations

Patient Information

- Name
- Date of Birth
- Gender assigned at birth, preferred pronouns

Notes to include:

- Describe the chief complaint, specifying which hand(s) exhibit tremor (if applicable)
- Include the patient's diagnosis, including time since diagnosis and symptom progression
- Describe medical, surgical, and psychiatric history, including prior medication use (list of medications, dosage, etc.)
- Evaluate for potential contraindications to TAPS therapy (e.g., seizure history, pregnancy, or implanted electrical medical devices such as a pacemaker, defibrillator, insulin pump, or deep brain stimulator)
- Describe family and social history
- Describe the physical examination of the patient, including strength, sensation, reflexes, balance, gross and fine motor control, as well as tremor evaluation impacts on activities of daily living (e.g., ability to hold a cup of water, draw a spiral, write a sentence)
- Describe the impacts of hand tremors on quality of life—whether and what kind of assistance is required (including information provided by caregiver (if present)
- Provide the patient's/family's goals—describe the activity and quantify assistance and/or outcome.
- Include OT/PT evaluation, if available.
- Describe other treatment interventions such as prior medications (including whether they were effective, had side effects, etc.)
- Describe alcohol use, if relevant
- Describe contraindications for medication therapy or other interventions that have been attempted (e.g., wrist weights, weighted utensils, etc.).

Plan:

- Consider whether to prescribe TAPS therapy
- Consider a return for follow-up re-evaluation in 6-8 weeks after obtaining the TAPS device

Cala Customer Care

Patient Intake and Agreement Form

Submit completed forms via:
Fax: 1-833-230-9251
Encrypted Email: Intake@CalaHealth.com
Secure Upload: CalaRx.com
Health Care Professional Line: 1-888-585-7101
Cala Customer Care: 1-888-699-1009

1. Patient Information

First Name:		Last Name:	
Date of Birth:		Gender: ☐ Male ☐ Female	
Address:		Email:	
City:		State:	Zip:
Primary Phone:		Home Phone:	
Emergency Contact Name:		Emergency Contact Phone:	

2. Insurance Information

2a. Primary Insurance information			**2b. Secondary Insurance Information**		
Insurance Provider:			Insurance Provider:		
Policy ID	Group #:		Policy ID:	Group #:	
Address:			Address:		
City:	State:	Zip:	City:	State:	Zip:
Benefits Phone:			Benefits Phone:		
Policy Holder Name:			Policy Holder Name		
Policy Holder Date of Birth: Relationship to Patient: ☐ Self ☐ Spouse ☐ Parent ☐ Guardian			Policy Holder Date of Birth: Relationship to Patient: ☐ Self ☐ Spouse ☐ Parent ☐ Guardian		

3. Patient Authorization & Agreement

I acknowledge that I have been provided with the following notices by accessing the company website or in writing (upon request) and understand notices may be revised from time to time: ***Notice of Privacy Practices (HIPAA), Returns and Warranty, and Therapy Terms of Use which include the Patient Bill of Rights and Responsibilities, and Complaint Process***.

I agree to all applicable terms outlined in this document's Patient Acknowledgment and Financial Responsibility sections.

I, or my representative, will promptly notify Cala if I stop using Cala TAPS therapy for any reason or am hospitalized for more than 30 days.

Patient Signature:	Date:
Personal representative: If the individual signing this form is not the patient, please print name and specify relationship to the patient; if Power of Attorney, please provide documentation.	
Personal Representative:	Date:

4. Patient Acknowledgements

a. I authorize Cala and its staff to provide me with durable medical equipment prescribed by my healthcare professional (HCP). My HCP has explained the nature of this treatment, and I have received sufficient information about the Cala TAPS Therapy to make an informed decision.

b. I authorize the release to Cala of any medical records for payment purposes, including but not limited to processing insurance claims. I also authorize Cala to share my medical records for healthcare operations and treatment purposes, including but not limited to sharing Cala TAPS therapy data with my prescribing HCP.

c. My HCP has screened me for the appropriateness of Cala TAPS Therapy. I do not have a cardiac pacemaker, implanted defibrillator, insulin pump, other implanted electronic device, or implanted metal in the wrist. I am not pregnant or have been suspected or diagnosed with epilepsy or other seizure disorder. I understand the device should not be used on swollen, infected, inflamed areas, skin eruptions, open wounds, or cancerous lesions. I will alert my HCP and Cala if my health condition changes such that therapy use is now contraindicated.

d. My HCP has explained the nature of this treatment, and I have received information about the Cala TAPS Therapy System and its appropriate and safe use. Upon receipt of my device, I understand that training is available to me by a Cala Customer Care Representative. I shall contact Cala Customer Care at 888-699-1009 Monday-Friday from 8 am – 7 pm Eastern, 5 am – 4 pm Pacific to schedule a training appointment.

e. I take full responsibility for the safe use and care of the Cala TAPS Therapy System (which includes the Cala Stimulator, Base Station, and Band). I will advise my HCP before discontinuing treatment or using the equipment. I shall not hold Cala responsible for any adverse consequences related to any misuse, failure to use, or discontinuation of the treatment. Cala maintains customer support by telephone at 888-699-1009 Monday-Friday from 8 am – 7 pm Eastern, 5 am – 4 pm Pacific. If a treatment reaction occurs when an HCP is absent or outside of Cala business hours, I will stop using the Cala TAPS Therapy System immediately and contact Cala Customer Care or my HCP before resuming use. If a life-threatening medical emergency arises, I will contact my local emergency services number, such as 911, for assistance.

f. **Medicare Beneficiary:** I understand the products and/or services provided by Cala are subject to the supplier standards contained in the Federal regulations shown at 42 Code of Federal Regulations Section 424.57(c). These standards concern business professional and operational matters (e.g., honoring warranties and hours of operation). The full text of these standards can be obtained at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-424/subpart-D/section-424.57. Upon request, I will be furnished with a paper copy of the standards.

g. **Out-of-Network:** If Cala is out-of-network with my insurance, I understand that my insurance may not cover any items or services furnished by Cala. I understand I may seek care from another in-network provider. Cala will make reasonable efforts to inform me of my insurance coverage and estimated out-of-pocket expenses before delivery.

h. **Results Not Guaranteed:** My HCP has prescribed Cala TAPS Therapy to deliver electrical stimulation to relieve hand tremor temporarily. I understand that this is not a cure for essential tremor. I also understand that individual patient results may vary, and no warranty or guarantee is made regarding my use of the Cala TAPS Therapy. I understand Cala TAPS therapy is intended for single patient use only and Cala Bands are provided with an initial three-month supply that must be replaced.

i. Return of Device to Cala: I understand that I cannot return any component of Cala TAPS Therapy for a refund unless the policy below permits.

For All Medicare Patients (Parts B and C Advantage): I understand that the 60-day return policy does not apply when using Medicare benefits. Cala will collect copay fees monthly based on my ongoing use of Cala TAPS therapy. Upon termination of therapy use, I will no longer be charged copay fees, and Cala will stop billing Medicare on my behalf. If I stop using therapy, I will notify Cala (Returns@CalaTrio.com) and return all therapy components to Cala.

For Commercially Insured Patients: I understand that within 60 days of receiving my initial Cala TAPS Therapy, I can return all system components for any reason by writing to (Returns@CalaTrio.com) and returning the equipment except when insurance contract terms supersede this policy. Any deductible and/or out-of-pocket expenses are collected upon receipt of the Explanation of Benefits issued by the insurer as defined by the cost identified in the patient responsibility section of the EOB. Please see the "Limited Warranty" section regarding repair and replacement.

For 100% Self-Pay Patients: Within 60 days of receiving Cala TAPS Therapy, I can return all system components for any reason by writing to (Returns@CalaTrio.com) and returning the equipment. After receiving the returned equipment, Cala will void all agreements and refund credit card charges.

For Veterans Affairs Patients Only: Within 90 days of receiving Cala TAPS Therapy, I may return all the components for any reason by writing to Cala (Returns@CalaTrio.com) and returning the equipment. The VA will be refunded on my behalf for returned product that complies with this policy.

5. Patient Financial Responsibilities (not applicable to Veterans Affairs Patients)

a. I assign to Cala all rights, benefits, and payments to which I am entitled under any benefit plan or insurance for items and services furnished to me or my dependents by Cala.

b. Accepting items and services from Cala means accepting my responsibility for any deductible, copay, and remaining balance due. I authorize Cala to inquire about, submit and appeal claims to my insurance for items and services received from Cala.

c. I authorize Cala to submit claims to my insurance on my behalf and my insurance to pay benefits directly to Cala. If I receive funds intended to pay, in whole or part, the forgoing claims, I will immediately pay over such funds to Cala to apply to any balance due.

d. I may revoke this authorization in writing to Cala. I assign Cala any legal or administrative claim or cause of action, including fiduciary duty claims, arising from any benefit plan or insurance concerning medical expenses incurred from items or services received from Cala.

e. I will promptly notify Cala of any changes to my insurance.

f. I accept full and complete financial responsibility for all charges for any or all components of the Cala TAPS Therapy System that are not covered by my insurance or for which I am responsible for payment under my insurance. Cala accepts VISA, MasterCard, American Express, and Discover Card for payment.