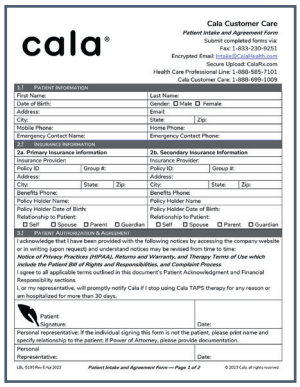
Prescribing Cala TAPS® Therapy

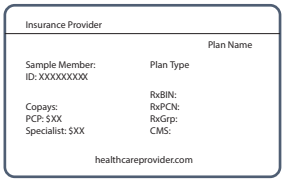
Thank you for your interest in the Cala kIQ® system with TAPS therapy, the next generation FDA-cleared wearable device with neuromodulation therapy for action hand tremors. To prescribe the Cala kIQ System for your patient, the following documents should be completed and sent to Cala:

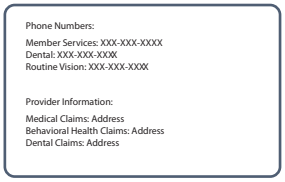
1. **Cala TAPS Therapy: Standard Written Order — Prescription Form**

2. **Patient-signed intake form**



3. **A copy of the front and back of the insurance card**





4. **Electronically signed chart notes with patient name, date of birth, assigned sex at birth, and the requirements for medical necessity**

When prescribing for Medicare Beneficiaries, please refer to the Medicare Local Coverage Determination (LCD) criteria (L39591) for specific documentation requirements.

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39591&ver=11

After receiving the completed documents, our team is committed to providing patients the support they need throughout their treatment journey, from submitting reimbursement to using therapy.

If you or your staff have any questions or concerns about your patient's Cala kIQ prescription, please do not hesitate to contact our Customer Care team at 888-699-1009 or CustomerCare@CalaHealth.com.

We look forward to working together to provide the best possible care for your patient.

Submit completed forms via: Fax: 1-833-230-9251 | Encrypted Email: Intake@CalaHealth.com | Secure Upload: CalaRx.com

Health Care Professional Line: 888-585-7101 | Cala Customer Care: 888-699-1009

1800 Gateway Drive | Suite 120 | San Mateo, CA | 94404

Indications for Use: Cala kIQ is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor. Cala kIQ is indicated to aid in the temporary relief of postural and kinetic hand tremor symptoms that impact some activities of daily living the treated hand following stimulation in adults with Parkinson's Disease.

Caution: Federal law restricts this device to sale by or on the order of a physician. Before use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at CalaHealth.com/Safety.

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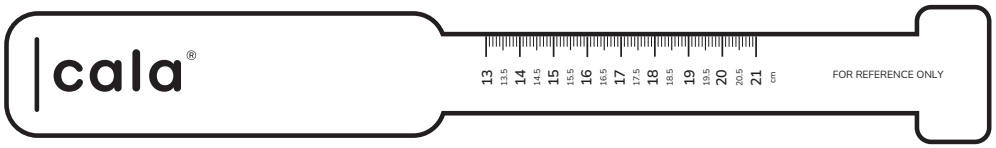
SD-20018 Rev C

cala®

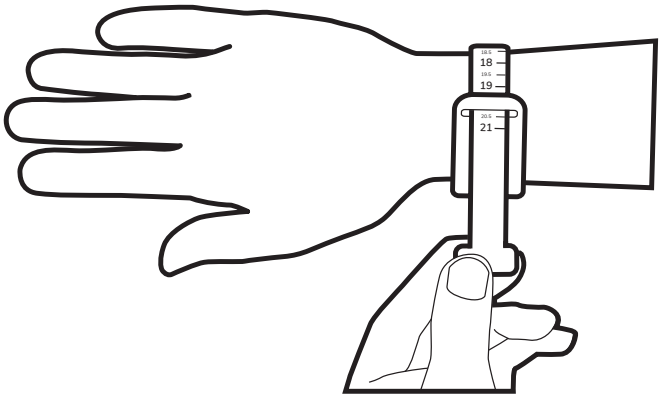
Measuring Wrist Size

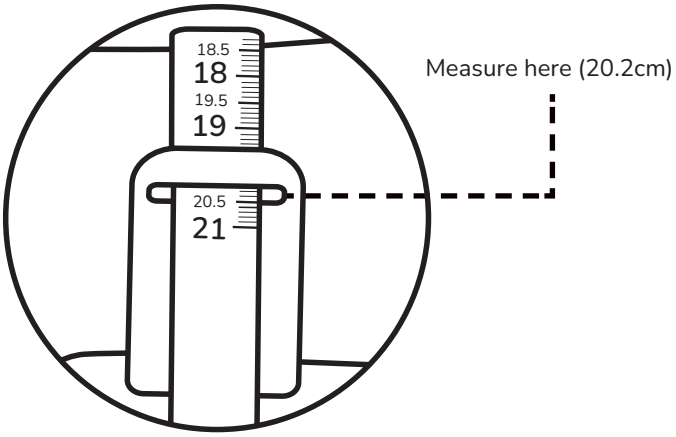
Capturing an accurate measure of your patient's wrist is important to ensure proper fit of the Cala kIQ® band for nerve targeting and therapy delivery. Cala provides a tool to help measure the patient's wrist size to input onto the prescription form (cm). A soft tape measure (tailor's tape, sewing tape, or paper measuring tape) may also be used. Please see the suggested approach below:



Position the measuring tool on the wrist as close to the hand as possible without impeding wrist movement. Should the patient have a prominent or protruding wrist bone, avoid measuring over it but rather measure proximal to the wrist bone.

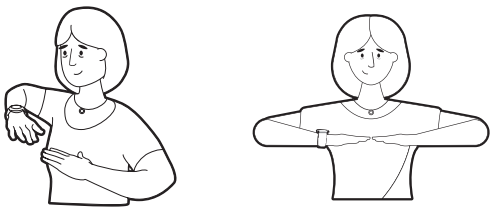
Hold the measuring tool tight to the skin, but do not squeeze wrist. Measure where the top of the slit sits on the tool markings, (not where the end of the tool sits on the markings). Note the size in cm on the patient's prescription form. Cala will use this to ship the correct size band to your patient.



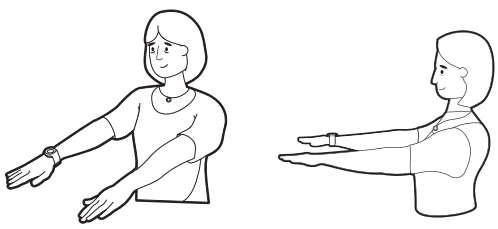


Selecting a Tremor Task

The Cala kIQ system calibrates therapy to each patient's unique tremor physiology based on a postural hold called a "tremor task". It is important for the prescribing clinician to indicate on the prescription form which tremor task **(wing-beating or outstretched hold)** predominantly elicits the hand tremor.



Wing-beating Postural Hold



Outstretched Postural Hold

CALA TAPS™ THERAPY: STANDARD WRITTEN ORDER—PRESCRIPTION FORM

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:	Sex: ☐ Male ☐ Female	
Address:	Email:	
City:	State:	Zip:
Mobile Phone:	Home Phone:	

PRESCRIPTION DETAILS (SELECT FROM EACH COLUMN)

Wrist Measurement*	Tremor Task**	Cala Stimulator (E0734)	Cala Bands (A4542)	Length of prescription
_____ centimeters	☐ Outstretched ☐ Wing Beating	Hand to treat: ☐ Left ☐ Right	Each band is a three-month supply	12 Month

* Please provide a measurement of the patient's wrist in centimeters. Using the measuring tool provided by Cala:
Position the measuring tool on the wrist as close to the hand as possible without impeding wrist movement.
Should the patient have a prominent or protruding wrist bone, avoid measuring over it but rather measure just proximal to the wrist bone.

** The Tremor Task is a postural hold that helps characterize the patient's tremor.
Please note which postural hold predominantly elicits the hand tremor.
Most patients use the outstretched postural hold.
If no task is selected, outstretched hold will be used as default tremor task.

Diagnosis ICD-10 Code:

☐ **G25.000 Essential tremor**

☐ **Other _____**

Contraindications:

A full list of contraindications, warnings, and cautions can be found at https://calahealth.com/safety

PRESCRIBER AUTHORIZATION

This document serves as a Standard Written Order and Prescription 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. I understand that my email address may be required for me to access Cala TAPS Therapy data for this patient.

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

SD-20016 Rev C

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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:
Mobile 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, Supplier Standards, 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. By providing your mobile phone number, you consent to receive autodialed text messages at that number from Cala Health concerning the Cala TAPS™ System. Consent is not required to purchase any goods or services. Text STOP to cancel. Message and data rates may apply.

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:

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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 appropriate and safe use of 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 understand that a full list of contraindications, warnings, and cautions can be found at!https://calahealth.com/terms/indications-for-use/. I acknowledge either that I do not have any contraindications, or I do have contraindications and have discussed these contraindications with my HCP. I will alert my HCP if my health condition changes such that therapy use becomes contraindicated.

d. 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 tremors. 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 s 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: 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@CalaHealth.com) and return all therapy components to Cala.

j. For Commercially Insured and Medicare Advantage Patients: I understand that there is no trial period. Please see the "Limited Warranty" section regarding repair and replacement at https://calahealth.com/terms/returns-warranty/.

k. For 100% Self-Pay Patients: Within 60 days of receiving Cala TAPS Therapy, I can return certain system components for any reason by writing to (Returns@CalaHealth.com) and returning the equipment. The bands are not eligible for return or refund. After receiving the stimulator and base station, Cala will void all agreements and refund credit card charges accordingly.

l. 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@CalaHealth.com) and returning the equipment. The VA will be refunded on my behalf for returned product that complies with this policy.

m. The Cala Health product you receive may include refurbished components. By signing this form, you acknowledge and agree to this. All refurbished products have been tested and inspected by Cala Health to ensure they meet our quality and safety standards. If you have any questions, please contact Cala Customer Care.

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.

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Patient Name _____

DOB _____

(or affix chart sticker here)

APPENDIX A:

Bain Findley Activities of Daily Living (BF-ADL)[1]

For each item circle the number which describes how easy or difficult it is for you to perform the activity.

Task Number	Task Description	Initial Appt Score **Date of Completion:** _____	Follow Up Appt Score **Date of Completion:** _____
1	Cut food with a knife and fork	1 2 3 4	1 2 3 4
2	Use a spoon to drink soup	1 2 3 4	1 2 3 4
3	Hold a cup of tea	1 2 3 4	1 2 3 4
4	Pour milk from a bottle or carton	1 2 3 4	1 2 3 4
5	Wash and dry dishes	1 2 3 4	1 2 3 4
6	Brush your teeth	1 2 3 4	1 2 3 4
7	Use a handkerchief to blow your nose	1 2 3 4	1 2 3 4
8	Use a bath	1 2 3 4	1 2 3 4
9	Use the lavatory	1 2 3 4	1 2 3 4
10	Wash your face and hands	1 2 3 4	1 2 3 4
11	Tie up your shoelaces	1 2 3 4	1 2 3 4
12	Do up buttons	1 2 3 4	1 2 3 4
13	Do up a zip	1 2 3 4	1 2 3 4
14	Write a letter	1 2 3 4	1 2 3 4
15	Put a letter in an envelope	1 2 3 4	1 2 3 4
16	Hold and read a newspaper	1 2 3 4	1 2 3 4
17	Dial a telephone	1 2 3 4	1 2 3 4
18	Make yourself understood on the telephone	1 2 3 4	1 2 3 4
19	Watch television	1 2 3 4	1 2 3 4
20	Pick up your change in a shop	1 2 3 4	1 2 3 4
21	Insert an electric plug into a socket	1 2 3 4	1 2 3 4
22	Unlock your front door with the key	1 2 3 4	1 2 3 4
23	Walk up and down stairs	1 2 3 4	1 2 3 4
24	Get up out of an armchair	1 2 3 4	1 2 3 4
25	Carry a full shopping bag	1 2 3 4	1 2 3 4
Total Score:			

KEY:

Score	Score Description
1	Able to do the activity without difficulty
2	Able to do the activity with a little effort
3	Able to do the activity with a lot of effort
4	Cannot do the activity by yourself

1.Bain PG, Findley LJ, Atchison P, et al. Assessing tremor severity. *Journal of Neurology, Neurosurgery & Psychiatry.* 1993;56(8):868-73.