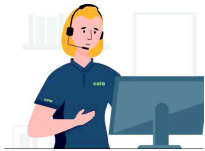




VA Cala kIQ Ordering Process for Prosthetics Department

Thank you for your interest in Cala kIQ™, a TAPS (Transcutaneous Afferent Patterned Stimulation) next generation FDA-cleared wearable neuromodulation therapy for action hand tremors. This letter outlines the process for placing a PO for the Cala kIQ System.



1. VA Facility Set-Up as New Vendor



2. Provider sends consult to prosthetics



3. Prosthetics Submits PO to Cala



4. Cala or VA Ships Device & Trains Patient (*varies by VA)

1. New Vendor Set-Up. To be completed by prosthetics department.

- Complete Form W-9 Cala and VA New Vendor Form with pre-filled Cala info.
- Refer to VA SOP Topic: *Non-Invasive Nerve Stimulation for Management of Tremor*.

2. Consult. Provider (neurologist, occupational therapist, etc) sends consult to prosthetics.

- Consult includes prescribed hand, tremor task, and wrist measurement to be included with PO.

3. Send Purchase Order to Cala. To be completed by prosthetics department.

- Purchase Order that includes the following information:
 - Patient information: name, address, DOB, phone number, last 4 digits SSN, email
 - Diagnosis & device information: patient diagnosis, contraindications, prescribed hand, tremor task, wrist size, quantity
 - VA information: consulting provider name and NPI, name & email, VA institution name, VA credit card

4. Patient Shipped & Trained on Cala kIQ System. Process varies by VA.

- Cala Ship to Patient Home & Train: If your VA is set up to have Cala ship the device, Cala will reach out to patient for shipping and training options.
- Cala Ships to VA to Deliver & Train Patient: If your VA is set up to provide the device, then Cala will ship devices to VA facility and the patient may schedule a time directly with the VA to receive the device and training.

For questions about pricing and POs, please call Cala Customer Care at (888-699-1009) Monday through Friday, 8 am – 7 pm Eastern, 5 am – 4 pm Pacific, or send an encrypted email: VA@CalaHealth.com.

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

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. SD-20010 Rev A

Health Care Professional Line: 888-585-7101 | Cala Customer Care: 888-699-1009 | 1800 Gateway Drive | Suite 300 | San Mateo, CA | 94404

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Cala Codes for New Vendor Setup

Cala is a licensed U.S. Durable Medical Equipment (DME) provider

DUNS Number	078877556	CMS Issued HCPCS Codes for Cala Devices	
CAGE code	6XN36	K1018	External Upper Limb Tremor Stimulator of the Peripheral Nerves of the Wrist. Covers the stimulator and base station
UID	PUKZNB5PY96	K1019	Replacement Supplies and Accessories for External Upper Limb Tremor Stimulator of the Peripheral Nerves of the Wrist. Covers monthly band subscription supplied every 90 days.

Initial Purchase Order

The initial Purchase Order must contain the following information:

Item Number	Description	Quantity Ordered	Unit	Negotiated Unit Price	Amount
1	Cala Therapy Stimulator & Charging/Base Station	1	Each	\$3,200	\$3,200
2	Cala Therapy Band* 1 band = 3-mo supply OR 4 bands = 12-mo supply <ul style="list-style-type: none"> Specify: Right -OR- Left Hand -OR- Bilateral Tremor Task: Outstretched -OR- Wing-Beating Wrist Measurement in Centimeters 	4*	Each	\$470	\$1,880
	Total (Includes Shipping)				\$5,080

IMPORTANT: Each Cala band must be replaced every 90 days because it deteriorates with exposure to dry skin, skin oils, and dust. The stimulator will not function with the same band after 90 days. The prescription is good for 1 year, and 4 bands are needed for the veteran to have a full year of therapy.

IMPORTANT: Required information to be included on the purchase order:

Patient Name	Prescribed Hand (Right, Left, or Bilateral)	VA Prescriber NPI
Patient Date of Birth (D.O.B.)	Tremor Task (outstretched or wing beating postural hold)	VA Credit Card Number
Patient Phone Number	Wrist Measurement in Centimeters	VA Credit Card Expiration Date
Patient Email Address (if available)	VA Institution Name	VA Credit Card CVV (optional)
Patient Diagnosis	VA Prescriber Name	VA Credit Card Zip Code
Patient Shipping Address	VA Prescriber Email Address	Caregiver Contact Email and/or Phone # (if applicable)

How to Send an Order

Fax: (833) 230-9251 Secure Upload: CalaRX.com Send Encrypted Email with attachments: VA@CalaHealth.com

IMPORTANT: It is advised to have the patient sign their Patient Intake and Agreement form during their clinic visit with the prescribing provider to prevent treatment delay. To expedite product shipment, please fax the completed form to Cala (833) 230-9251. Product shipment may be made to Veterans home or VA center as determined by prescribing provider, and the correct "Ship To" address must be included on the PO.

Returns & Warranty

Cala offers a 90-day return option due to the heterogeneous nature of action tremors of the hand - not all patients may benefit from the use of Cala devices. If the Veteran discontinues use within the 90-day trial period, Cala will fully refund the costs. Credit will be applied to the VA credit card within 30 days once Cala receives the Cala Stimulator/Base Station and all bands.

The Cala kIQ System is designed for use on demand. The stimulator and base station have an expected service life of 3 years. The band has an expected service life of 90 days. To support everyday use, the stimulator has a 2-year warranty, and the band has a 45-day warranty.

For more, please visit CalaHealth.com/Warranty



VA Consult for Ordering the Cala kIQ System

Thank you for your interest in Cala kIQ™, a TAPS (Transcutaneous Afferent Patterned Stimulation) next generation FDA-cleared wearable neuromodulation therapy for action hand tremors. To order the Cala kIQ System for your patient, a consult to prosthetics and a patient intake form are required.

The Cala kIQ System is for people with action hand tremors, a diagnosis of either essential tremor or Parkinson's disease and have tried or cannot tolerate pharmacological interventions.

Refer to the VA SOP Topic: Non-invasive Nerve Stimulation for Management of Tremor for more information.

1. Patient Intake and Agreement Form - Signed by Patient

- Include name of prescribing provider
- Include last 4 digits of patient SSN
- Send to Cala at time of consult through one of the following channels:
 - Fax: 1-833-230-9251
 - Encrypted Email: VA@CalaHealth.com
 - Secure Upload: CalaRx.com

2. Consult - Include the following information when submitting for a prosthetics consult. If prescribing for both hands, two devices are needed - one dedicated to each hand.

- Prescribed hand (left and/or right)
- Tremor task (outstretched or wing beating postural hold)
- Wrist measurement in centimeters
- Name of prescribing provider
- Number of bands included in order*
 - 1 Band = 3 Months of Therapy
 - 4 Bands = 12 Months of Therapy

*Number of bands in consult determines when the next consult is required for the patient to continue therapy.

If you or your staff have any questions or concerns about your patient's Cala kIQ order, 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.

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. SD-20011 Rev A

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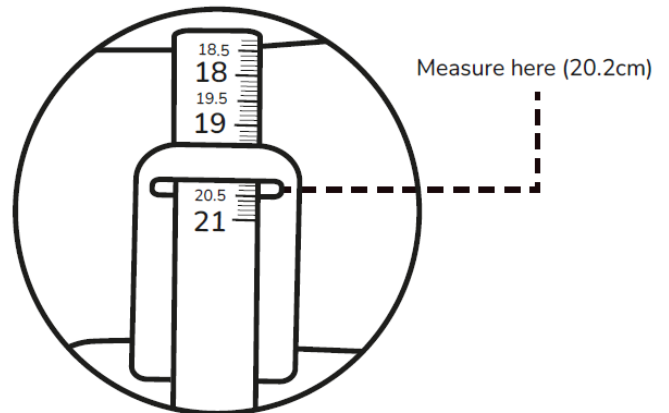
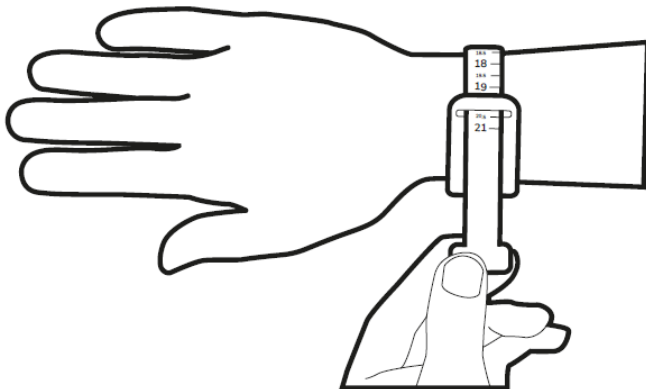
Measuring Wrist Size

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:



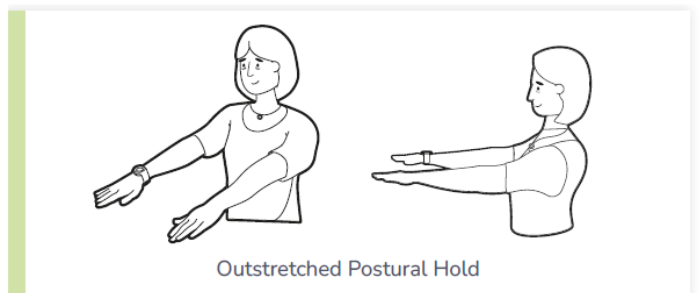
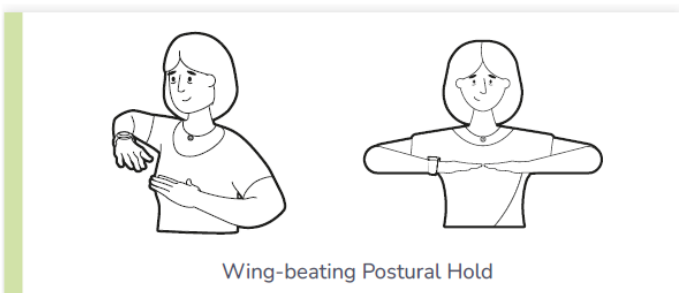
Position the measuring tool on the wrist as close to the hand as possible without impeding wrist movement. Should the patient have a prominent or protruding wrist bone, avoid measuring over it but rather measure proximal to the wrist bone.

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.





Cala Customer Care

Patient Intake and Agreement Form

Submit completed forms via:

Fax: 1-833-230-9251

Encrypted Email: VA@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: <input type="checkbox"/> Male <input type="checkbox"/> Female	
Address:		
City:	State:	Zip:
Mobile Phone:	Home Phone:	
Email Address:		
Emergency Contact Name:		
Emergency Contact Phone:	Last 4 Digits Patient SSN:	
Prescribing Provider Name:		

2. 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:
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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 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.