cala

Cala Customer Care
Standard Written Order & Prescription Form

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

PATIENT INFORMATION

First Name _____

Last Name _____

Date of Birth _____ Gender M ☐ / F ☐

Email _____

Address _____

City _____ State _____ Zip _____

Primary Phone _____

Home Phone _____

INDICATIONS FOR USE

To aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor (ET). Cala therapy delivers Transcutaneous Afferent Patterned Stimulation (TAPS).
Caution: Federal law restricts this device to sale by or on the order of a physician.

DIAGNOSIS

ICD-10 Code:

☐ G25.000 *Essential tremor* ☐ Other _____

☐ *Check if you are including the patient's medical history and chart notes of patient's last 3 office visits. Be advised, your patient will experience significant delays in accessing Cala TAPS therapy through insurance benefits if they are not included with this form.*

CONTRAINDICATIONS

Cala TAPS Therapy should NOT be used:

- by patients with an implanted electrical medical device, such as a pacemaker, defibrillator, bladder stimulator, or deep brain stimulator.
- by patients that have suspected or diagnosed epilepsy or other seizure disorder.
- by patients who are pregnant.
- on swollen, infected, inflamed areas, or skin eruptions, open wounds, or cancerous lesions.

PRESCRIBING INFORMATION

Measurement	Tremor Task*	Hand	Cala™ Stimulator (K1018)	Cala™ Bands (K1019)	Length of Prescription
_____ ☐ cm ☐ in Please provide a measurement of the patient's wrist in centimeters or inches. Measure the patient's wrist circumference proximal to the head of the ulna to determine band size.	Outstretched ☐	Right ☐	1	4 Each band is a three month supply = 3 monthly units	12 months
	Wing Beating ☐	Left ☐	1		
		Right & Left ☐	2	8 Each band is a three month supply = 3 monthly units	

To ensure measuring accuracy please print on 8.5" x 11" paper and confirm printer calibrations are properly aligned

* 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 hold wing beating.

PRESCRIBER AUTHORIZATION

I hereby attest that this order accurately reflects signatures/notations that I made in my capacity as the above-mentioned Medicare beneficiary's healthcare provider. I do hereby attest that this information is true, accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability. I therefore prescribe Cala TAPS therapy.

Prescriber's Signature _____ Date _____

First Name _____ Last Name _____ (Circle: MD/DO/CRNP/PA)

NPI# _____ Practice Name/Institution _____

PRESCRIBER CONTACT INFORMATION

Office Contact Person _____ Office Contact Phone _____

Address _____ City _____

State _____ Zip _____ Email _____

Phone _____ Fax _____

TRANSCUTANEOUS AFFERENT PATTERNED STIMULATION (TAPS) MEDICARE CLINICAL DOCUMENTATION GUIDE

Overview:

A patient's medical records are expected to reflect the need for the care you provide and equipment you recommend. Your documentation is the most important factor to successful coverage and payment of your patient's claim. It must support the fact that billed services and/or equipment are medically necessary, skilled medical services, and are certified by the physician.

For Medicare to cover a Transcutaneous Afferent Patterned Stimulation (TAPS) device such as the Cala Trio™, the patient must qualify through individual consideration. Documentation must indicate he/she has a movement limitation that significantly impairs his/her ability to participate in one or more activities of daily living (ADLs) or instrumental activities of daily living (IADLs) including but not limited to feeding, dressing, writing, personal hygiene and grooming, bathing/showering, toilet hygiene, personal device care etc.). Therefore, there must be sufficient evidence in the patient's medical records through documentation showing the patient's movement limitation(s) and explaining interventions attempted to ameliorate the limitation including resultant outcomes.

Documentation for DME justification may include one or more of the following: physician's office records (e.g., most recent history/physical, annual examination, progress reports), records from specialists (neurology, neurosurgery, etc.) and other health care professionals (e.g., physical or occupational therapy (PT/OT) evaluation, daily notes), test reports (e.g., Thyroid function lab studies, MRI, EEG, DaTscan, etc.), hospital records (e.g. admit/discharge note, surgical/test reports), home health agency records, nursing home records, etc.

Supplier and/or manufacturer generated forms, even if completed or signed by the physician, non-physician provider (NPP) or therapist, are not substitutes for medical record documentation and are not accepted by CMS, as sufficient to support medical need. However, these documents are often important supportive corroborative documentation to supplement the medical records.

Medically necessary durable medical equipment, such as a wearable neuromodulation device, for Medicare beneficiaries must be prescribed by a physician, physician assistant, nurse practitioner, or clinical nurse specialist. **The physician may perform the evaluation *or* refer the patient to a qualified licensed certified medical professional (LCMP) such as a physical therapist or occupational therapist who has experience and training in functional movement evaluations, to perform part of the evaluation. The PT or OT must have no financial relationship with the supplier or manufacturer.**

Medicare Policy Resources

For further guidance on compliance with CMS DME policies, see the Medicare Program Integrity Manual (Chapter 5, Section 5.9.2)

TRANSCUTANEOUS AFFERENT PATTERNED STIMULATION (TAPS)
MEDICARE CLINICAL DOCUMENTATION GUIDE

Sample: Office Visit Note - Electronic Health Record

[Patient Name]'s chief complaint is tremor of the hands.

[Patient's/Family's Goal] "I want to be able to **(describe activity and quantify assistance and/or outcome e.g., write checks/drink coffee without spilling/eat independently, etc.)."**

[Background] The patient is a ____-year-old right/left-handed woman/ man **(sex/ gender info)** who was referred by ___ for evaluation of dominant hand tremor. A tremor in the patient's dominant hand began ___ years ago. The patient was diagnosed with essential tremor (ICD10-G250) on ____**(date),** and the tremor has been **(describe course of progression e.g., progressively worsening over the past X years despite increasing medications, etc.).** Tremor is also present in the non-dominant hand, though it has less impact on activities of daily living.

[Patient Name] was accompanied by **[his/her/their] [spouse/adult relative/caregiver]** who can attest that the hand tremors are interfering with Activities of Daily Living requiring regular assistance from a caregiver. Whereas the patient was previously independent, they now require assistance with the following activities **(specify activity e.g., eating, drinking, bathing, dressing, writing, or other fine motor skills AND assistance needed e.g., hand over hand assist, minimal, moderate, maximum assistance)**.

History and Physical:

- Medical, surgical, and psychiatric history: _____
- Family and Social history: _____
- Physical examination of the patient: Neuro exam including strength, sensation, reflexes, balance, gross and fine motor control, as well as tremor evaluation (ability to hold a cup of water, draw a spiral, write a sentence)
- Include OT/PT evaluation, if available.

Assessment:

Essential Tremor G25.0, dominant hand that is interfering with ADLs and is medically refractory.

The patient has tried and failed the trials of oral medications: **name of the drug, dose, duration of therapy, side effects if any** OR patient is contraindicated for first- and second-line medications (e.g., due to comorbidities). They have also tried and failed other treatment interventions such as (specify- e.g., wrist weights, weighted utensils, etc.).

This patient does not have implanted electrical medical devices such as a pacemaker, defibrillator, or deep brain stimulator. There is no history of seizure disorder. (If female, the patient is currently not pregnant).

Comorbid conditions such as anxiety or depression are present and can potentially be addressed with effective tremor therapy.

Plan:

1. Rx for TAPS for ___hand (specify side to be treated), _____cm wrist size and tremor inducing task outstretched/wing beating (select postural hold that helps characterize patient's tremor)
2. Rx for one TAPS electrode wrist band a three-month supply
3. Return for follow up re-evaluation in 6-8 weeks after obtaining TAPS device.

For additional information on the elements of a comprehensive evaluation for Wearable Neuromodulation Device (WMD) please see the following Clinical Documentation Guide for greater detail and description.

WEARABLE NEUROMODULATION DEVICE CLINICAL DOCUMENTATION GUIDE

Your evaluation and medical documentation must demonstrate the patient's need for the recommended Durable Medical Equipment (DME)-wearable neuromodulation device (WND) based on the patient's health condition, diagnosis, functional prognosis, and factors that indicate treatment effectiveness and outcomes.

A goal of medically appropriate WND is for the patient to return to the highest level of activity realistically attainable within the context of the patient's health condition and environment. Your documentation must show the results of your medical evaluation and should include the patient's medical status, movement, and function; and identify, recommend, and justify appropriate interventions such as medication, WMD or surgical interventions.

Covered DME such as Transcutaneous Afferent Patterned Stimulation (TAPS) must relate directly and specifically to an active written plan of care and must be reasonable and necessary to the treatment of the individual's illness or injury. Address in the plan of care specific patient goals for which the type, frequency, and duration of treatment interventions are outlined. The plan of care must be certified/approved by the physician or non-physician provider.

Provide in your report information about the following elements as well as other relevant details. Each element does not have to be addressed in every evaluation; however, it is beneficial to acknowledge that it was considered and not applicable.

Intake and History: Describe patient's history/progression of present illness and movement problem(s), reason for referral, current functional status, activities/participation on a typical day including limitations and restrictions. Include as much objective information as possible.	
Who was present	Name who is present during the examination (clinician, family, caregiver)
Demographic information	General demographics such as name, age, sex, height, weight
Referral mechanism	Self-referral or request from another practitioner (specify)
Referring medical diagnosis	Onset date, prognosis, and progression, specifying ICD-10 codes, related to Essential Tremor (ICD10- G250)
Medical/surgical history	Pertinent history related to movement limitation (e.g., essential tremor)
Family history	Pertinent family history related to movement limitation (e.g., essential tremor)
Reason for referral/chief complaint	Functional movement problem(s), assistance, medications, and/or devices needed, what has changed to now require a new intervention and/or device.
History of movement limitation	Progression of movement limitation, technology used/tried, medical/surgical/treatment interventions, results of interventions
Contraindications for TAPS	Rule out implanted electrical medical devices (pacemaker, defibrillator, DBS), epilepsy, pregnancy
Treatment diagnosis/ICD-10 related to movement limitation(s)	ICD-10 that support medical necessity- e.g., Essential Tremor G25.000, Other _____ specifying left, right, or bilateral
Patient/family/caregiver goals	Goals for Transcutaneous Afferent Patterned Stimulation (TAPS)
Social status	Living situation (e.g., lives alone, lives with family, receives attendant care including hours/week and assistance provided- specify tasks)
Employment/work status (job/school)	Occupation (typical job duties), school/work tasks, functions
General health status	Social/health habits (past/current) caffeine and alcohol intake, fatigue, anxiety
Functional status and activity level (Self-care, domestic life activities, interpersonal relationships, and prior mobility)	Routine daily activities (medical appointments, cooking/cleaning/laundry, grocery shopping, recreation), roles/responsibilities (parent, primary caregiver, head of household), prior level of functioning, falls history
Equipment Assessment: Provide equipment-specific information.	
Existing Assistive Devices	Adaptive weighted utensils, weights, other (describe)
Functional Assessment: Include subjective and objective evaluations of performance and functional abilities to establish activity level, level of movement impairment, and indicate the prognosis for potential restoration of function. May refer to PT/OT for this portion of the evaluation.	
ADL/IADL status	Describe assistance and quantify (e.g., time) needed to perform ADLs/IADLs (e.g., Bain and Findley Activities of Daily Living) and specify equipment used if any (e.g., weighted utensils, handle build ups, etc.)
Endurance	Activity tolerance, duration, intensity prior to fatigue

Screening of Body Systems: This may require further physical examination, collaboration, or referral.	
Cardiovascular/pulmonary/ circulatory status	Heart rate, BP, respiratory rate, etc.
GI system review	Swallow, digestion (reflux), constitutional
Cognitive status	Memory skills, problem solving, attention/concentration, learning skills
Physical Examination and Test & Measures: Focus on body systems that are responsible for the patient's movement limitation.	
Sensation	Intact, impaired, absent, location (describe)
Pain	Location, severity, what exacerbates/what relieves
Skin integrity	Skin inspection: (e.g., swollen, infected, inflamed areas, open wounds or cancerous lesions)
Balance	Static and dynamic sitting/standing balance, supports needed
Strength	Manual muscle test, muscular endurance
Range of motion	Muscle length and joint mobility/flexibility of extremities and trunk that impacts movement
Neuromuscular status	Cranial nerves, muscle tone, reflexive responses, coordination, motor control, effect on function
Tremor	● Characterize tremor, (postural, rest or action), ● Frequency (slow, intermediate, rapid), ● Amplitude (fine, medium, coarse) speed, ● Unifocal, multifocal or generalized, ● Location (head, face, jaw, voice, tongue, trunk or extremities, ● Tremor scale assessment e.g., TETRAS / FTM)
Assessment: Describe past and planned intervention options, what worked, what did not, and why.	
Medication Trials and Results	Medication trials (dosage, frequency, duration, results)
Other interventions	● Referrals to OT/PT (dates, duration, results), ● adaptive equipment (adaptive utensils, weighted devices, etc.), ● provide evaluation notes/findings if available
Recommendations and Rationale	Discuss benefits/risks of intervention options features (e.g. DBS, MRgFUS, TAPs) with patient/family and identify technology features needed to attain identified goals
Evaluation and Plan of Care: Describe goals, treatment procedures/interventions, recommended equipment, clinical rationale, duration/frequency required to attain goals, anticipated follow up and plan.	
Diagnosis related to movement limitation	Factors that are influencing the individual's condition and/or level of functioning in his or her environment. Diagnosis ICD-10 code must correspond to Essential Tremor G25.000
Problem list	Identification of problems pertinent to patient management/clinical services and medically necessary recommended TAPS (e.g., medically refractory tremor, anxiety, depression, etc.)
Goals for TAPS intervention	A realistic evaluation of the patient's functional potential with the use of the recommended equipment, stated in measurable terms related to functional activity (e.g., food/drink consumption, hygiene, writing, etc.)
Plan for interventions and/or additional test and measures	Refer to PT or OT for functional evaluation and/or equipment recommendations, Refer for TAPS device SPECIFY REQUIRED PARAMETERS (frequency, duration, Left/Right/Bilateral) ● Handedness: Left -OR- Right, ● Wrist circumference measurements in cm____, ● Tremor inducing task: outstretched -OR- wing beating
Equipment recommendation, feature specification, clinical rationale	Details of recommended equipment, features (Stimulator, Bands) and clinical rationale for items requested
Prognosis	Predicted outcome based on TAPS recommendation