
Medical Policy



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***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: External Upper Limb Tremor Stimulator (e.g., Cala ONE™, Cala Trio™)

Description/Background

Essential Tremor

Essential tremor is a neurological disease that causes tremor, characterized as movement that is rhythmic and involuntary, most commonly in the hands and/or arms. Tremors can cause impaired fine motor coordination (such as those needed to eat or work), ataxia, or abnormal gait. Exacerbating factors may include stress, anxiety, excessive caffeine, hot or cold temperatures, hunger, and smoking cigarettes. Other terms for essential tremor include benign essential tremor, familial tremor, and hereditary essential tremor.

Diagnosis

Diagnosis is based upon clinical evaluation of signs and symptoms. No specific imaging or laboratory tests to diagnose essential tremor currently exist. Clinical diagnostic criteria proposed by the Movement Disorders Society require that the tremor:¹

1. "[Be an] isolated tremor syndrome of bilateral upper limb action tremor
2. "[Have] at least 3 years' duration
3. "[Occur] with or without tremor in other locations (e.g., head, voice, or lower limbs)
4. "[Have an] absence of other neurological signs, such as dystonia, ataxia, or parkinsonism."

Treatment

Treatment for essential tremor is intended to reduce tremors. Mild essential tremor may not require any treatment if symptoms do not interfere with daily activities or function. Lifestyle interventions may include avoiding known triggers (e.g., cigarettes, caffeine), practicing relaxation techniques and/or anxiety management, using modified implements (e.g., eating utensils), or weighting the limbs. First-line treatment is typically pharmacotherapy, such as propranolol and/or primidone. Second-line pharmacotherapy may include additional beta-blockers, levetiracetam, benzodiazepines, or botulinum toxin. For patients for whom

pharmacotherapy does not confer adequate symptom relief, thalamic deep brain stimulation may be prescribed. Thalamotomy is a surgical procedure involving brain destruction that is typically only considered for patients with severe symptoms refractive to other therapies due to its invasiveness and risky adverse event profile.¹

Cala One™/Cala Trio™

Cala Trio by Cala Health Inc. is an external upper limb tremor stimulator. The small device resembles a smartwatch in appearance and is worn on the wrist of the patient to administer neuromodulation, with the intent of reducing essential tremors. This device has been referred to in the literature and online using generic terms as transcutaneous afferent pattern stimulator and external upper limb tremor stimulator.

The device administers electrical stimulation to the median and radial nerves in the wrist, which is relayed through the nervous system to the brain and proposed to disrupt the neural network such that tremors are reduced temporarily. Patients can wear the device and administer neuromodulation as needed in any setting and are advised to use it approximately 40 minutes before attempting tasks with which the tremor interferes.²

Regulatory Status

Cala ONE is regulated as a class II device under regulation 21 CFR 882.5897. The original device by Cala Health was cleared for marketing under a de novo classification request and assigned product code QBC. This code defines an external upper limb tremor stimulator, which according to the classification request is "a prescription device which is placed externally on the upper limb and designed to aid in tremor symptom relief of the upper limb."

Two 510(k) clearances were subsequently granted—most recently in 2021—including name rebranding to Cala Trio. Other changes in the clearances appear to primarily be design modifications deemed substantially equivalent and not expected to impact safety or effectiveness.

Medical Policy Statement

The use of an essential upper limb tremor stimulator for essential tremors is experimental/investigational. Its effectiveness in this clinical indication has not been scientifically determined.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

E0734

A4542

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Evidence reviews assess whether a therapy is clinically useful. A useful therapy provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the therapy is used to manage the condition than when another therapy or no therapy is used to manage the condition.

Clinical Context and Therapy Purpose

Cala Trio is a self-administered neuromodulation therapy that uses a small and noninvasive portable device in an outpatient setting with the intent of reducing tremors in patients with essential tremor.

Populations

The relevant population of interest is individuals with essential tremor.

Interventions

The intervention is the Cala Trio, an external upper limb tremor stimulator.

Comparators

Comparators of interest is the standard treatment for essential tremors (i.e., lifestyle interventions, practicing relaxation techniques and/or anxiety management, using modified implements (e.g., eating utensils), pharmacotherapy, and/or thalamic deep brain stimulation.

Outcomes

The overall outcomes include the safety of the therapy, any adverse events associated with the therapy, decrease in the amount or severity of tremors and an increase in functional status.

Review of Literature

Isaacson et al (2020) reported on a prospective study on home-use of non-invasive neuromodulation therapy for ET.³ This was a prospective, open-label, post-clearance, single-arm study with 263 patients enrolled across 26 sites. Patients were instructed to use the therapy twice daily for three months. Pre-specified co-primary endpoints were improvements

on clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS)¹ and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Other endpoints included improvement in the tremor power detected by an accelerometer on the therapeutic device, Clinical and Patient Global Impression scores (CGI-I, PGI-I), and Quality of Life in Essential Tremor (QUEST) survey. Two hundred five patients completed the study. The co-primary endpoints were met ($p < 0.0001$), with 62% (TETRAS) and 68% (BF-ADL) of 'severe' or 'moderate' patients improving to 'mild' or 'slight'. Clinicians (CGI-I) reported improvement in 68% of patients, 60% (PGI-I) of patients reported improvement, and QUEST improved ($p = 0.0019$). Wrist-worn accelerometer recordings before and after 21,806 therapy sessions showed that 92% of patients improved, and 54% of patients experienced $\geq 50\%$ improvement in tremor power. Device-related adverse events (e.g., wrist discomfort, skin irritation, pain) occurred in 18% of patients. Future work examining how these clinical trial results translate into the real-world setting would be valuable.

Pawah et al (2019) conducted a randomized controlled trial to evaluate the safety and effectiveness of a wrist-worn peripheral nerve stimulator (PNS) in patients with essential tremor (ET).⁴ This was a randomized controlled study of 77 ET patients who received either treatment stimulation ($N = 40$) or sham stimulation ($N = 37$) on the wrist of the hand with more severe tremor. Tremor was evaluated before and immediately after the end of a single 40-minute stimulation session. The primary endpoint compared spiral drawing in the stimulated hand using the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral scores in treatment and sham groups. Additional endpoints included TETRAS upper limb tremor scores, subject-rated tasks from the Bain and Findley activities of daily living (ADL) scale before and after stimulation as well as clinical global impression-improvement (CGI-I) rating after stimulation. Subjects who received PNS did not show significantly larger improvement in the Archimedes spiral task compared to sham but did show improvement in upper limb TETRAS tremor scores ($p = 0.017$) compared to sham. Subject-rated improvements in ADLs were greater with treatment (49% reduction) than with sham (27% reduction; $p = 0.001$). A greater percentage of ET patients (88%) reported improvement in the stimulation group as compared to the sham group (62%) according to CGI-I ratings ($p = 0.019$). No significant adverse events were reported; 3% of subjects experienced mild adverse events. Although the results are encouraging, future studies are needed to confirm the effectiveness of this noninvasive therapy over time.

Barath and colleagues (2020) reported an interventional, open-label, single-group study investigating the changes in brain metabolism over 3 months of TAPS use in 5 ET ($n=5$) participants.⁵ Each participant received 40 minutes of TAPS treatment twice daily for 90 days. Brain metabolic activity and tremor severity were measured at baseline, and after 90 days using F-fluorodeoxyglucose (FDG) PET/CT and TETRAS. The participant's tremor power and frequency were measured before and after therapy sessions. Inclusion criteria were ≥ 21 years of age and approved for DBS surgery by the Mayo Clinic DBS Committee for treatment of ET. Participants were excluded if they had alcohol dependence or had an implanted pacemaker, defibrillator, or deep brain stimulator. The mean age of the study participants was 70.2 ± 5.2 years, and the duration of ET ranged from 10 to 57 years (mean 32 ± 16.8 years). Participants enrolled for approximately 89.2 ± 4.8 days and completed 136.2 ± 41.3 TAPS sessions; participant compliance was $77.3 \pm 25.6\%$. The FDG PET/CT results demonstrated areas of increased metabolism in the ipsilateral cerebellar hemisphere and decreased metabolism in

¹ TETRAS is an x-item questionnaire using finger to nose motions, not resting tremor.

the contralateral hemisphere following 90 days of therapy, compared to day 1 ($p < 0.05$). Comparison of pre- and post-therapy measurements over 90 days showed decreased tremor power ($p < 0.0001$), but no change in frequency. The day 1 TETRAS scores decreased from 6.5 to 4.1 following TAPS ($p = 0.05$). The 90-day pre- and post-TETRAS scores also decreased from 4.9 to 4.1 ($p = 0.14$ and $p = 0.05$, respectively). No adverse events were reported. The authors concluded that longitudinal TAPS of the median and radial nerves affect brain metabolism in areas necessary for motor coordination which may cause ET. Study limitations included its small study population and weak power. Additional studies with robust methodology and power are needed to further elucidate the clinical mechanism of TAPS.

Yu and colleagues (2020) reported a single-arm, open-label study, of 15 individuals with ET who received TAPS therapy.⁶ The aim was to evaluate the duration of tremor reduction. Inclusion criteria were individuals 22 years of age and older diagnosed with ET by an internist or neurologist. Participants performed four hand tremor-specific tasks (postural hold, spiral drawing, finger-to-nose reach, and pouring) from the Fahn-Tolosa-Marin Clinical Rating Scale (FTM-CRS) prior to, during, and 0, 30, and 60 minutes following TAPS therapy. Tremor severity was rated using the FTM-CRS, and simultaneously with wrist-worn accelerometers. The duration of tremor reduction was measured by improvement in the mean FTM-CRS score across all four tasks compared to baseline, and reduction in accelerometer-measured tremor power compared to baseline for each task. The results demonstrated that mean FTM-CRS scores improved for at least 60 minutes beyond the end of TAPS for 80% of participants. For the assessed tasks, tremor power improved for at least 60 minutes beyond the end of TAPS for over 70% of participants. The postural hold task had the most significant reduction in tremor power (median 5.9-fold peak reduction in tremor power) and had at least 60 minutes of improvement relative to baseline beyond the end of TAPS therapy for 73% of participants. No adverse events were reported. The authors concluded that tremor power is a valid, objective assessment metric, and that TAPS therapy may improve upper limb tremor symptoms for at least 1 hour post therapy which may improve ability to perform ADL's in individuals with ET. The authors also noted that 5 of the 15 subjects in this study who were on pharmacologic treatment for ET, may have ingested medication that could have influenced the duration of effect. The NIH considers TETRAS the superior ET assessment measure compared to FTM, stating "TETRAS has two main advantages over FTM in the assessment of tremor severity: (1) the absence of a ceiling effect in patients with severe ET, and (2) the inclusion of wing-beating tremor". While the results of this study are promising, larger cohorts with similar ET tremor scales are needed to further evaluate the clinical utility of TAPS.

Table 1. Strengths and Limitations of the Studies

Author	Study Design	Strengths	Limitations
Isaacson et al (2020)	Prospective pretest-posttest study	• Prospective • Moderate-to-large sample size • Standard instruments	• No control group • >20% attrition • Potential author conflicts of interest (manufacturer affiliations); study supported by Cala Health
Pawah et al (2019)	Randomized controlled trial	• Random Allocation • Sham control • Participants and outcomes assessors masked to treatment group • Standard outcome measures	• Only single session of tx with no further follow-up; informs feasibility but not efficacy or safety. • Total global TETRAS and BF-ADL scores NR

			Potential author conflicts of interest (manufacturer affiliations); study supported by Cala Health
Barath et al (2020)	Open label single group study		- Small study group (5 subjects) - No sham control group - Open label
Yu et al (2020)	Open label single session study		- Small study group - No sham control group - Single session with no further follow-up

Fraile et al (2019) conducted a systematic literature review was conducted using standardized criteria regarding efficacy and comfortability.⁷ Devices focused on design or experimental testing in which tremor was simulated in a robot were excluded. Out of 324 articles initially identified, 12 articles were included. Orthoses using biomechanical loading and neuromodulation with electrical stimulation, and external tremor cancelation devices, were the main interventions used to suppress tremor. All devices were designed to control tremor of the upper limbs at different anatomical locations. Overall, an average tremor attenuation of 50–98% was reported (level of evidence III). Interference with voluntary movements and portability was described as the main drawback. In conclusion, this review highlights the growing interest in emerging tremor control devices and the importance of assessing comfort without affecting voluntary movements. However, the level of evidence regarding the efficacy of these tremor control devices remains low. An integrated multidisciplinary combination approach of engineering, robotics, physiology, physiotherapy, and clinical assessment is needed to improve the quality of non-pharmacological interventions for ET.

SUMMARY OF EVIDENCE

For individuals who have ET and are willing and able to use the device, the evidence includes one prospective study, one RCT and one systematic literature review. Although the results of the RCT and prospective study are encouraging, future studies are needed to confirm the effectiveness of this noninvasive therapy over time. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Essential Tremor Foundation

In 2021, the International Essential Tremor Foundation issued a statement “Cala Trio (and/or other noninvasive devices) is noted as a potential part of management of essential tremor, as an add-on to first- or second-line pharmacotherapy.” This statement was based on expert opinion.⁸

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
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Ongoing			
NCT03778060	Long term transcutaneous stimulation and essential tremor: a PET study	20	Dec 2022

Government Regulations

National:

No NCD was identified for this device/service for essential tremor.

Local:

LCD L39591. External Upper Limb Tremor Stimulator Therapy. Effective 04/07/2024.¹²

INITIAL COVERAGE:

An external upper limb tremor stimulator of the peripheral nerves of the wrist (E0734) is covered when the beneficiary has had a clinical evaluation (in-person or via Medicare-approved telehealth) by the treating practitioner, and all of the following criteria are met (See the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article):

1. The beneficiary has a diagnosis of essential tremor (ET) (Refer to the Group 1 ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary is 18 years or older; and,
3. The beneficiary has no contraindications to external upper limb tremor stimulator therapy; and
4. The external upper limb tremor stimulator is being prescribed to treat the beneficiary's dominant upper limb; and,
5. The severity of ET symptoms significantly impairs the beneficiary's ability to perform dominant hand, upper-limb-related activities of daily living (ADLs) as indicated by a score of greater than or equal to 3 on the Bain & Findley Tremor ADL Scale (BF-ADL) for at least one (1) assessment item for eating, drinking, self-care, or writing (See Appendix A); and,
6. If medically appropriate, tremor exacerbating medications (e.g., stimulants, beta agonists) have been reduced or eliminated; and,
7. At least two (2) pharmacological treatment options for the management of ET symptoms have been either tried and failed at maximal tolerable treatment dosages (i.e., no or limited effect, intolerable side effects) or considered and ruled out (e.g., not appropriate in the context of the beneficiary's medical history); and,
8. External upper limb tremor stimulator therapy is being prescribed as an alternative to invasive and/or permanent surgical treatment options (e.g., deep brain stimulation, magnetic resonance guided focused ultrasound, radiosurgery).

When an external upper limb tremor stimulator (E0734) is covered, the supplies and accessories (A4542) will also be covered.

If all of the initial coverage criteria 1 through 8 are not met, claims for codes E0734 and A4542 will be denied as not reasonable and necessary.

An external upper limb tremor stimulator (E0734) for the non-dominant upper limb will be denied as not reasonable and necessary.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of external upper limb tremor stimulator therapy, and related supplies and accessories (E0734 and A4542) beyond the first three (3) months of therapy requires that no sooner than the 60th day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation (in-person or via Medicare-approved telehealth) and document that the beneficiary is:

1. Deriving benefit from external upper limb tremor stimulator therapy as indicated by a 1-point improvement in BF-ADL score in any eating, drinking, self-care, or writing task scored as greater than or equal to 3 prior to the initiation of therapy; and,
2. Adhering to external upper limb tremor stimulator therapy (adherence is defined as use of external upper limb tremor stimulator therapy on 70% of the days during a consecutive thirty (30) day period anytime during the first three (3) months of initial use).

If the treating practitioner's clinical re-evaluation does not occur until after the 91st day, but the re-evaluation demonstrates that the beneficiary is benefiting from and adhering to external upper limb tremor stimulator therapy, continued coverage of external upper limb tremor stimulator therapy will commence with the date of that re-evaluation.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Deep Brain Stimulation
- Transcranial Stimulation
- Interferential Stimulation
- Peripheral Subcutaneous Field Stimulation

References

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7. Fraile VC, Pena EC, Galan JM, Tremor control device for essential tremor: a systematic literature review. Tremor and Other Hyperkinetic Movements; December 2019;9 doi:10.7916/tohm. v0.688.
8. International Essential Tremor Foundation. Coping with essential tremor. <https://www.essentialtremor.org>. Accessed March 2025.
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11. Valdunciel AP, Hoo GW, Avrillion S, et al. Peripheral electrical stimulation to reduce pathological tremor: a review. J Neuroengineering Rehabil; 2021; 18:33.
12. CGS Administrators, LLC. Local Coverage Determination (L39591). External Upper Limb Tremor Stimulator. Effective on or after 04/07/2024. Accessed March 2025.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/22	4/19/22		Joint policy established
7/1/23	4/18/23		Received literature for review, literature discussed. Routine policy maintenance, no change in policy status. Vendor managed: Northwood (ds)
7/1/24	4/16/24		Codes K1018 & K1019 deleted, replaced with codes E0734 & A4542. Updated rationale, added references 5, 6 & 12. Vendor managed: Northwood (ds)
7/1/25	4/15/25		Policy replaced with new policy titled "Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation (e.g., Cefaly®, Cala ONE™, Cala TRIO™, eTNS, Axon)," effective 7/1/25. Vendor managed: Northwood (ds)

Next Review Date:

This policy is replaced with new policy, "Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation (e.g., Cefaly®, Cala ONE™, Cala TRIO™, eTNS, Axon)," effective 7/1/25

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: EXTERNAL UPPER LIMB TREMOR STIMULATOR (E.G., CALA ONE™, CALA TRIO™)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.