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Medicare Coverage Criteria for TAPS® Therapy[1]

Medicare may provide coverage for external upper limb tremor stimulator therapy, also known as TAPS (Transcutaneous Afferent Patterned Stimulation) therapy, according to criteria effective as of April 7, 2024 (Local Coverage Determination LCD L39591).[2]

The following information describes the Medicare coverage criteria and documentation requirements applicable to TAPS therapy devices for patients with Essential Tremor (ET).

A. Criteria for Initial Medicare Coverage of TAPS Therapy

Medicare coverage may be available if the beneficiary with ET has had a clinical evaluation (in-person or via Medicare-approved telehealth) by the treating practitioner, and all of the following coverage criteria are met and documented in the medical record:

1. The beneficiary has a diagnosis of essential tremor (ET); 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 TAPS therapy 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 (1: no difficulty doing the activity, 4: cannot do the activity alone due to tremor) (Refer to LCD L39591 Appendix A); AND
6. If medically appropriate, tremor exacerbating medications (eg. stimulants, beta agonists) have been reduced or eliminated; AND
7. At least two pharmacological treatment options for the management of ET symptoms have been either tried and failed at maximal tolerable dosages (i.e., no or limited effect, intolerable side effects) OR considered and ruled out (e.g., not appropriate in context of the beneficiary's medical history); AND
8. TAPS therapy is prescribed as an alternative to invasive and/or permanent surgical treatment options (e.g., deep brain stimulation, magnetic resonance guided focused ultrasound, radiosurgery).

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Medicare Coverage Criteria for TAPS® Therapy[1] (cont.)

B. Continued Medicare Coverage Beyond First Three Months

Continued Medicare coverage of TAPS therapy 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) to determine and document whether the beneficiary is:

1. Deriving benefit from TAPS therapy as indicated by a 1-point improvement in the BF-ADL score in any eating, drinking, self care OR writing task scored as ≥ 3 prior to the initiation of therapy; AND
2. Adhering to therapy defined as use of TAPS therapy on 70% of days during a consecutive thirty (30) day period anytime during the first three (3) months of initial use.

Access the Medicare Local Coverage Determination Criteria and Guidelines for External Upper Limb Tremor Stimulator Therapy (l39591)

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

[1] Patients must meet Medicare eligibility criteria. Local Coverage Determination (LCD): External Upper Limb Tremor Stimulator Therapy (l39591) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39591&ver=11&bc=0 (for services performed on or after April 7, 2024).

[2] It is ultimately the responsibility of the treating HCP to determine and document the appropriate diagnoses and code(s) for the patient's condition. There is no guarantee that the use of any information provided in this document will result in coverage or payment by any third-party payor. Each healthcare provider is ultimately responsible for verifying codes, coverage, and payment policies used to ensure that they are accurate for the services and items provided. As a courtesy, Cala provides the most up-to-date information available, but it is subject to change and interpretation. Cala does not guarantee third-party coverage of payment for any items or services.

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