

Cala Receives Pricing from CMS for Cala TAPS Therapy to Expand Medicare Patient Access

Benefit category designation and payment determination expands patient access to the only FDA-cleared non-invasive targeted therapy for hand tremor

SAN MATEO, CA – Oct. 11 -- [Cala](#), the bioelectronic medicine leader setting a new standard of patient care for chronic disease, today announced that the Centers for Medicare & Medicaid Services (CMS) has set a payment determination and benefit category for the existing unique Healthcare Common Procedure Coding System (HCPCS) code K1018 for Cala TAPS therapy, initially put into effect in 2021. This decision, effective October 1, 2022, expands access for Medicare patients with essential tremor (ET) who could benefit from Cala TAPS therapy.

Cala TAPS therapy, delivered by the Cala Trio device, is the only FDA-cleared bioelectronic therapy that's clinically proven to be safe and effective for relief of hand tremor among adult patients with ET. Many patients prefer TAPS, or Transcutaneous Afferent Patterned Stimulation over pharmaceutical and surgical options because patients control their own therapy sessions on the wearable device whenever they want tremor reduction. Unlike prescription drugs, it does not cause systemic side effects or drug-to-drug interactions.

"The momentum continues to build for Cala TAPS therapy," said Renee Ryan, CEO of Cala Health. "This pricing decision from CMS will make it easier for Medicare beneficiaries to access this important therapy to treat essential tremor. Appropriate pricing for Cala TAPS therapy is a great step in expanding access and rewarding innovation for clinically proven treatment options outside of pharmacological options or invasive surgery."

Across the United States, up to 10 million people live with ET, [most commonly affecting people older than 65](#). The PROSPECT study, published in *Tremor*, is the largest therapeutic ET study to date, and underscores Cala TAPS therapy as a safe and effective option for patients.¹ Cala TAPS therapy is a recommended therapeutic option for patients with ET in guidelines published by the International Essential Tremor Foundation (IETF).²

"Cala TAPS therapy is life-changing for many of my patients living with essential tremor," said Dr. Stuart Isaacson, Director and Founder of the Parkinson's Disease and Movement Disorders Center of Boca Raton. "It's important for patients to have affordable, routine, and easy access to this novel treatment option."

The ruling from CMS reinforces the value of Cala TAPS therapy and is a critical step forward to ensuring that Medicare patients have access to the therapy. On behalf of the patient, Cala can now submit claims to the Durable Medical Equipment Medicare Administrative

¹ Isaacson, S. H., Peckham, E., Tse, W., Waln, O., Way, C., Petrossian, M. T., ... Pahwa, R. (2020). Prospective Home-use Study on Non-invasive Neuromodulation Therapy for Essential Tremor. *Tremor and Other Hyperkinetic Movements*, 10, 29. DOI: <http://doi.org/10.5334/tohm.59>

² International Essential Tremor Foundation. (2021). *Essential Tremor in Adult Patients [IETF Guideline]*. <http://eguideline.guidelinecentral.com/i/1380755-essential-tremor-advisory-ietf/0>

Contractors (DME MACs) for individual patient determination and can support patients by providing greater visibility into their financial obligations for the therapy.

About Cala Health

Cala is a bioelectronic medicine company transforming the standard of care for chronic disease. The company developed a unique therapeutic approach, Transcutaneous Afferent Patterned Stimulation (TAPS), to target the source of tremor and deliver individualized relief as needed. Cala TAPS therapy, delivered by the Cala Trio device, is the only FDA-cleared, clinically validated bioelectronic therapy for hand tremor relief for patients with essential tremor. New approaches are in development to applying TAPS to Parkinson's disease, as well as other applications in neurology, psychiatry, cardiology and autoimmune disorders. Founded in 2014, the company is headquartered in the San Francisco Bay Area and backed by leading investors in both healthcare and technology.

Indication: The Cala Trio device is indicated to aid in the temporary relief of hand tremors in the treated hand following stimulation in adults with essential tremor.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Prior to use, refer to the product labeling for complete product instructions for use, contraindications, warnings, and precautions at <https://calatrio.com/Safety>.

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