

Cala TAPS Therapy for Essential Tremor Patients Improves Outcomes in a New Randomized Controlled Trial

Cala continues to expand patient access to TAPS therapy and receives an upgraded clinical evidence assessment from ECRI

SAN MATEO, CA – March 23, 2023 -- Cala, the bioelectronic medicine leader setting a new standard of care for chronic disease, today announced meeting the primary endpoint on an interim analysis of a prospective, randomized, controlled study. This study, “RWE Study Utilizing the Cala Trio Device in Patients With Essential Tremor” (clinicaltrials.gov NCT05540626), demonstrated that adding TAPS therapy to the patient’s care plan improved outcomes.

The study met its primary endpoint, demonstrating patients adding TAPS therapy had significantly reduced (i.e. improved) tremor power than patients not adding TAPS therapy to their care plan ($p < .0001$) in the first 261 patients who have completed the randomized portion of the study. 84% of patients experienced tremor reduction and 43% of patients experienced greater than 2-fold tremor improvement (i.e. 50% tremor reduction) after a single month of therapy ($p = 0.0047$). Patients adding TAPS therapy also had significantly greater improvement in Bain & Findley Activities of Daily Living (ADL). Additionally, patients using TAPS therapy experienced significantly improved tremor power before and after TAPS ($p < 0.0001$) and significantly reduced baseline tremor only with 1 month of repeated use ($p = 0.0018$).

These findings were presented at the Academy of Managed Care Pharmacy (AMCP) on March 23, 2023, which recognized the abstract with a Bronze ribbon award for its relevance, originality, quality, bias and clarity.

“There is a significant unmet need for patients living with essential tremor, which is often disabling,” said Stuart Isaacson, MD, Board-certified Movement Disorder Neurologist, Director, Parkinson’s Disease and Movement Disorders Center of Boca Raton. “Drug therapy is only variably effective and associated with difficult to tolerate side effects, leading to high discontinuation rates. These results demonstrate that adding Cala TAPS therapy improves patient outcomes in a real-world setting.”

Additional validation for TAPS therapy recently came from ECRI, the global independent nonprofit authority on healthcare technology and safety. ECRI recently upgraded its assessment of the clinical evidence supporting TAPS therapy (scoring 4 on a 5 point scale).

Medicare also recently recognized the unique value of TAPS therapy through new national pricing. Additionally, Cala TAPS therapy is now in-network with several Blue Cross Blue Shield health plans, Zellis and MultiPlan. The company is committed to expanding coverage and reimbursement options to enable healthcare professionals and patients to more easily access TAPS therapy.

Cala TAPS therapy will also be presented at the upcoming American Academy of Neurology Annual Meeting (AAN) on April 22-27, 2023 in Boston, including an emerging technology presentation by Kate Rosenbluth, Founder and Chief Scientific Officer and two study abstracts. Come visit us at booth 961.

About Cala

Cala Health is a bioelectronic medicine company transforming the standard of care for chronic disease. The company's wearable neuromodulation therapies merge innovations in neuroscience and technology to deliver individualized peripheral nerve stimulation, and its direct-to-home digital DME platform is reshaping the delivery of prescription therapies. Cala Health's lead product, Cala Trio™, is the only FDA-cleared, clinically validated non-invasive device for the relief of hand tremors so patients with essential tremor can return to the moments that matter. New therapies are under development in neurology, cardiology and psychiatry. 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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