Cranial Electrostimulation Therapy (CES)

Effective: January 1, 2026

Next Review: November 2026
Last Review: December 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cranial electrostimulation therapy (CES), also called cranial electrotherapy stimulation, involves passing small electrical impulses across the head, usually from electrodes placed on or near both ears.

MEDICAL POLICY CRITERIA

Cranial electrostimulation therapy is considered **investigational** for all indications, including but not limited to treatment of:

A. Alzheimer's disease
B. Anxiety
C. Apathy related to traumatic brain injury
D. Chemical dependence / substance abuse
E. Chronic pain related to spinal cord injury
F. Cognitive dysfunction
G. Depressive symptoms
H. Fibromyalgia

I. Headache
J. Irritable Bowel Syndrome (IBS)
K. Smoking cessation
L. Sleep disturbances
M. Stress related conditions
N. Tinnitus
O. Traumatic brain injury

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

POLICY GUIDELINES

Some cranial electrostimulation therapy (CES) devices may also be FDA approved to apply electrical stimulation to peripheral nerves [e.g., transcutaneous electrical nerve stimulation (TENS)]. This policy addresses cranial electrical stimulation that targets the brain only; electrical stimulation of peripheral nerves for the treatment of pain or other indications is addressed in separate policies (see Medical Policy, see Cross References, DME-83 for an index of other electrical stimulation policies).

CROSS REFERENCES

1. Microcurrent Stimulation (MENS), Durable Medical Equipment, Policy No. 83.03
2. External Trigeminal Nerve Stimulation for the Treatment of Attention Deficit Hyperactivity Disorder, Durable Medical Equipment, Policy No. 83.14

BACKGROUND

Although the mechanism of action is not clearly understood, it is hypothesized that electrical currents emitted from CES may positively impact the limbic system, the reticular activating system and/or the hypothalamus, resetting the brain to improved homeostasis levels.[1]

CES is proposed for use in treating a variety of chronic conditions including, but not limited to stress, alcoholism and drug addiction, headache, cognitive dysfunction in head injured patients, psychiatric conditions, irritable bowel syndrome, reflex sympathetic dystrophy and multiple sclerosis. Because many of these indications require long-term therapy with medications which may be costly, CES has been proposed as a cost-effective, non-invasive alternative to standard treatment.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has granted 510(k)* approval for a number of cranial electrotherapy stimulators including, but not limited to the following:

- Alpha-Stim® Cs (Electromedical Products, Inc)
- BR-2 Biorest (Biorest, Inc)
- Biotron18 (Biotronics Corp)
- CES Ultra ™ (Neuro-Fitness, LLC)
- Elexoma Medic (Redplane AG)

- FM 10/C (Johari Digital Healthcare, Ltd)
- HP-1 Healthpax or Nurtipax (Health Directions, Inc)
- LB-2000 (Life Balance Intl., Inc)
- LISS SBI202-B and SBI201-M (Medical Consultants Intl., Ltd)
- Modius Sleep (Neurovalens, Ltd)
- NET-2000 Microcurrent Stimulator (Auri-Stim Medical, Inc)
- NF-1 Mindpeace (NeuroFitness)
- NH 2002 (Life Balance Intl., Inc.)
- NTI-1000 (Neurotek, Inc)
- TESA-1 (Kalaco Scientific, Inc.)

*Marketing clearance via the 510(k) process does not require data regarding clinical efficacy.

In June of 2019, the FDA granted De Novo approval of the IB-Stim (Innovative Health Solutions) to aid in the reduction of functional abdominal pain in patients 11-18 years of age with irritable bowel syndrome (IBS). The device subsequently was reclassified to a Class II device with the broader regulation name of "non-implanted nerve stimulator for functional abdominal pain relief".[2] In 2024, IB-Stim received FDA 510(k) clearance for use in adolescents age 8 to 21 for functional abdominal pain relief.

EVIDENCE SUMMARY

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo. Treatment of mood disorders (anxiety, depression) and chemical dependency issues require the same level of evidence to ensure valid conclusions regarding superiority over placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared to other forms of conservative therapy such as pain medications. In patients with mood disorders or chemical dependency issues, treatment must be compared with the standard of care: psychotherapy or behavioral therapy, respectively, with or without medication.

SYSTEMATIC REVIEWS

Ching (2022) published a systematic review (SR) with meta-analysis of CES in the treatment of anxiety with a secondary outcome of CES on depressive symptoms.[3] To be included, studies met the following eligibility criteria: RCTs investigating the effects of CES as monotherapy or combination with other treatment (e.g., biofeedback therapy and antidepressants) for management of anxiety symptoms; (ii) diagnosis of anxiety disorders which meet the criteria in DSM-IV, DSM-IV TR, DSM-V or ICD10; (iii) the definition of anxiety symptoms based on screening tool; (iv) a comparison between an intervention group and a control group (e.g., biofeedback therapy, antidepressants); (v) sufficient data for both the intervention group and

the control group; (vi) articles written in English.CES significantly improved anxiety symptoms with moderate effect size (number of trials=11, n=692, Hedge's g=−0.625, 95% confidence interval [CI] = −0.952 to −0.298, p<0.001) compared to control/sham group. Additionally, CES significantly reduced depressive symptoms in patients with anxiety disorders (number of trials=8, n=552, Hedges' g=−0.648, 95% CI = −1.062 to −0.234, p=0.002;) compared to control/sham group. Significant heterogeneity was noted for both outcomes. The majority of the studies used Alpha-stim products. Limitations included five out of 11 students (45.4%) had an overall RoB2 ranking of some risk of bias concerns, studies used different stimulation protocols and the protocols were only used for acute treatment, limiting the ability to evaluate long term outcomes. The authors note that the placebo affect is a critical issue in these types of studies.

Price (2021) published a SR with meta-analyses of CES (Alpha-Stim) for the treatment of depression.[4] Two separate meta-analyses were conducted, one on data from RCTs (five studies, n=242) and another on data from non-randomized studies (12 studies, n = 1173). To be considered as a RCT, trials were required to have subjects blinded, a sham versus active condition, use of valid and reliable measurement instruments, at a minimum, a pretest-posttest design (additional repeated measures were acceptable), and rated as “good” or “fair” in a scoring system in which scoring categories were 0 to 1 limitations (rating = good); 2 to 4 limitations (rating = fair); 5 to 9 limitations (rating = limited). Due to variation in reporting of results across the five RCTs, only the difference at posttest between groups was used in the calculation of the effect of Alpha-Stim CES on depression. The average (population) effect for the five RCTs was d=−0.69 (i.e., the mean depression level at posttest for the active group was −0.69 standard deviations lower than the mean depression level for the sham group), which is considered a medium effect in favor of the treatment group. Analysis of the nonrandomized study data revealed an average (population) effect of d=−0.43, which is a small effect size. Significant heterogeneity for the effect sizes was found for this analysis. Limitations in the available RCT data include the small samples of patients who met DSM-V criteria for major depressive disorder. The systematic review and meta-analyses were sponsored by Electromedical Products International, Inc. and several study authors are affiliated with the company.

Yu (2020) published a SR with meta-analysis of noninvasive brain stimulation in the treatment of neuropathic pain in individuals with spinal cord injury was evaluated.[5] Although 11 studies of various noninvasive brain stimulation treatments were included, only one used CES as the intervention.[6] The pooled analysis found no significant effect of any of the treatment modalities on neuropathic pain reduction after spinal cord injury. While no beneficial effect over sham stimulation was found for depression scales, reduction in anxiety immediately following CES treatment was identified. The authors concluded that their findings do not support the routine use of noninvasive brain stimulation for neuropathic pain in individuals with spinal cord injury.

Shekelle (2018) published a SR for the Department of Veterans Affairs Evidence-based Synthesis Program (ESP) on CES for chronic pain, depression, anxiety, insomnia, and posttraumatic stress disorder (PTSD).[7] The authors identified 28 RCTs that met inclusion criteria. A meta-analysis could not be completed because there were too few studies of the same patient population and treatment protocol. The quality of all included RCTs was found to be low, and all had a high risk of bias. Therefore, although the results of the included RCTs indicated that CES may have a modest beneficial effect on symptoms of anxiety and depression in selected patients, the authors urged caution in interpreting the results.

A Cochrane SR and meta-analysis evaluated the use of CES as a non-invasive treatment for chronic pain, originally published in 2011 and updated in 2014 and again in 2018.[8-10] No differences were found in health outcomes when CES was compared with sham in the 11 studies that met the inclusion criteria. The review concluded that all available studies were at risk of bias, and that available data failed to suggest that CES provided a clear benefit over sham treatment.

Boldt (2014) evaluated non-pharmacological interventions for chronic pain in people with spinal cord injury in a Cochrane SR, including two trials that assessed the effects of transcranial direct current stimulation (tDCS), three trials that used repetitive transcranial magnetic stimulation (rTMS), and three studies that used CES.[11] In all of these trials sham controls were used. For the use of tDCS, the overall evidence for the effectiveness of tDCS in reducing chronic pain in spinal cord injury was scarce and inconclusive. For the use of rTMS, the data from the three studies was inconsistent regarding the treatments effectiveness in reducing chronic pain in this population. The two studies on CES had methodological limitations including selective reporting and imbalances in baseline characteristics between groups, and a third study was inconclusive.

Kavirajan (2014) published a Cochrane SR that assessed the efficacy and safety of CES as a treatment of acute depression compared to sham or simulated CES treatment.[12] Authors searched for properly blinded randomized trials of CES in adults aged 18-75 with depressive disorder, however, no studies met inclusion criteria. The authors concluded, “(t)here are insufficient methodologically rigorous studies of CES in treatment of acute depression. There is a need for double-blind RCTs of CES in the treatment of acute depression.”

A 2009 Cochrane SR for treatment of apathy in traumatic brain injury found only one RCT which met inclusion criteria for the review.[13] However, the reviewers cautioned against making conclusions from this RCT due to the small study size (n=21).

RANDOMIZED CONTROLLED TRIALS

Ilfeld (2025) conducted a double-blind RCT pilot study with the NSS-2 Bridge device in 30 patients undergoing primary, unilateral, total knee arthroplasty.[14] Treatment with the NSS-2 Bridge or sham stimulation was started in the recovery room and continued for five days. Median oxycodone consumption over the first five postoperative days was 4 mg with auricular nerve stimulation versus 13 mg with sham stimulation (p=0.039). Mean pain intensity over the first five postoperative days was 2.5 versus 4.0, respectively (p=0.014), on an 11-point numeric rating scale. No adverse events were reported. This study is limited by short-term follow-up and small sample size.

Ilfeld (2024) conducted a double-blind RCT pilot study with the NSS-2 Bridge device in 30 patients undergoing cholecystectomy and hernia repair.[15] Treatment with the NSS-2 Bridge or sham stimulation was started in the recovery room and continued for five days. Median oxycodone consumption over the first five postoperative days was 0 mg in both groups (p=0.524). Mean pain intensity over the first five postoperative days was 0.6 versus 2.6, respectively (p=0.041), on an 11-point numeric rating scale. Adverse events included device discontinuation due to electrode site discomfort (n=3) and electrode placement problems (n=3). This study is limited by short term follow-up and small sample size.

Morriss (2023) published a multi-center, double-blind RCT that investigated the effectiveness of the Alpha-Stim device in treating major depression in primary care.[16] Participants with

moderate to moderately severe primary major depression, who had not responded to antidepressant treatment, were randomly assigned to either active Alpha-Stim or sham Alpha-Stim treatment for eight weeks (n=118 each group). Stimulation was administered for one hour per day for eight weeks. Both treatment groups showed a clinically important decrease in the primary outcome, mean depression symptoms on the 17-item Hamilton Depression Rating Scale (HDRS-17) at four weeks, which was maintained at 8 and 16 weeks. However, there was no significant difference in the change in HDRS-17-measured symptoms at 16 weeks. Small changes, which were not clinically significant, were reported for the nine-item Patient Health Questionnaire (PHQ-9), the seven-item Generalized Anxiety Disorder scale (GAD-7), the eight-item Work and Social Adjustment Scale (WSAS), and the five-level EQ-5D (EQ-5D-5L) quality of life questionnaire. The study concluded that Alpha-Stim AID is a safe and well-tolerated treatment, but there is no evidence to support its clinical effectiveness in patients with moderate to moderately severe primary major depression.

Lee (2023) conducted an RCT to investigate the effectiveness of CES in reducing stress. Sixty-two adult participants, who experienced subjective stress combined with subclinical depression or insomnia, were randomly assigned to active CES or a sham procedure.[17] Participants used the device for 30 minutes twice per day for three weeks. Psychological rating scales, quantitative electroencephalography, and serial salivary cortisol levels were measured before and after the intervention. Immediately after the intervention, Beck depression inventory-II scores improved in both the CES and sham groups, but to a greater degree in the active CES group ($p<0.001$). CES led to a flattening of the cortisol slope ($p=0.011$) and an increase in bedtime cortisol ($p=0.036$) compared to the sham group. Limitations of this study include potential bias from participant-conducted CES, at-home sample collection, and lack of long-term follow-up.

A randomized controlled trial (RCT) by Kim (2021) evaluated CES as a treatment for anxiety in which nonclinical volunteers experiencing daily anxiety were randomly assigned to either active or sham groups[18]. Outcomes assessed after three weeks of 20 self-administered treatment sessions included the State-Trait Anxiety Inventory (STAI), Beck Depression Inventory (BDI), Wisconsin Card Sort Test (WCST), and resting-state electroencephalography (EEG). A significant improvement in state-anxiety was found in the active treatment group compared to sham, however, no significant difference in depression or WCST was found between groups. Increased EEG signal in specific brain regions in the active treatment group correlating to changes in state-anxiety were observed, the clinical utility of which is not clearly established. This study is limited by small sample size and no long-term outcomes.

Kovacic (2017) published the results of a RCT of the Neuro-Stim device for the treatment of abdominal pain-related functional gastrointestinal disorders in adolescents (aged 11-18 years).[19] Patients were randomly assigned (1:1) to an active stimulation or sham (no electrical charge) for four weeks and patient-reported worst abdominal pain and composite pain scores (Pain Frequency-Severity-Duration [PFSD] scale) were assessed as the primary outcomes. A total of 57 patients in the active treatment group and 47 patients in the sham group were included in the primary analysis. A greater reduction in worst pain after three weeks of treatment was found in the treatment compared to the sham group (treatment: median score 5.0 [IQR 4.0 to 7.0]; sham: 7.0 [5.0 to 9.0]; least square means estimate of change in worse pain 2.15 [95% CI 1.37 to 2.93], $p<0.0001$). PFSD composite scores also decreased significantly in the treatment group (from 24.5 [IQR 16.8 to 33.3] to 8.4 [3.2 to 16.2]) compared with sham (from 22.8 [IQR 8.4 to 38.2] to 15.2 [4.4 to 36.8]) with a mean decrease of 11.48 (95% CI 6.63 to 16.32; $p<0.0001$) after three weeks. These differences persisted into follow-up

(median follow-up 9.2 weeks [IQR 6.4 to 13.4]). There were no serious adverse events reported.

A subset analysis of the Kovacic RCT was published by Krasaelap (2020) which evaluated outcomes for patients with Irritable Bowel Syndrome (IBS), specifically.[20] This cohort consisted of patients who received active stimulation (n=27) or sham stimulation (n=23) for four weeks. The number of patients with a reduction of 30% or more in worst abdominal pain severity after three weeks was considered the primary outcome. Reduction in composite abdominal pain severity score, reduction in usual abdominal pain severity, and improvement in global symptom based on a symptom response scale after three weeks were evaluated as secondary outcomes. The primary outcome was found in 59% of patients who received the active stimulation and 26% of patients who received sham stimulation (p=0.024). Composite pain and usual pain median scores were reduced in the active stimulation compared to the sham group (p=0.026, 0.029, respectively). A symptom response scale score of two or more was observed in 82% of patients who received active treatment compared to 26% of patients in the sham group (p≤0.001). The authors reported no significant side effects. This study was limited by small sample size, lack of long-term follow-up, and specific endpoints not being defined *a priori*. The stimulation devices were provided by Innovative Health Solutions.

Roh and Wi-Young (2017) published a RCT that evaluated how CES effects symptoms of depression and anxiety, by evaluating behaviors and certain hormones[21] Fifty postmenopausal women received active CES (n=25) or a sham treatment (n=25). The active group received 20 minutes of CES three times a week for eight weeks. Cortisol, adrenocorticotropic hormone (ACTH), brain derived neurotrophic factor (BDNF), and nerve growth factor (NGF) levels were evaluated prior to the treatments and after the eight-week sessions. No differences in the levels were found. The CES group had less depression and tension-anxiety, but no changes were seen for anger-hostility, vigor-anxiety, fatigue-inertia, and confusion-bewilderment. This study had methodological limitations including small sample size and lack of long-term follow-up.

A number of RCTs explored the efficacy of CES for a variety of conditions not addressed in the Cochrane SRs noted above, including Alzheimer's disease, smoking cessation, anxiety in patients receiving dental care, preoperative anxiety, chemical dependence, sleep disturbances, fibromyalgia, constipation, dysfunctional gait, preoperative blood pressure, pediatric tic disorders, and tinnitus.[22-34] In addition, several RCTs not included in the reviews above were also identified.[35 36] Overall, data from these studies were unreliable due to a variety of limitations, including small study populations,[22-28 31 37 38] short follow-up of study subjects,[22-28 30 37-39] confounding use of co-therapies such as fibromyalgia medications[27] and antidepressants[35] , weak or unclear randomization methods,[22 25 27 28] and the use of flawed data analysis methodologies such as deleting a subset of patients based on their diagnosis after they had been randomized and treated[25], rendered the study findings unreliable.

Overall, the RCTs did not adequately explain the clinical significance of the changes observed in their outcomes of interest.[40] The treatment parameters used in the studies varied in their frequency, intensity, duration of individual CES sessions, as well as the overall treatment duration. Only two studies evaluated how changes in treatment parameters influenced the same outcome of interest. They did not find a significant difference between the two, but these studies were subject to other major design flaws.[22 23]

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of cranial electrical stimulation devices for the treatment of pain or any other indication.

SUMMARY

There is not enough research to show that cranial electrostimulation therapy (CES) improves health outcomes for people with pain or any other condition. In addition, no clinical guidelines based on research recommend CES as a treatment for any condition. Therefore, cranial electrostimulation therapy (CES) is considered investigational for all indications.

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CODES

Codes	Number	Description
CPT	~~0720T~~	~~Percutaneous electrical nerve field stimulation, cranial nerves, without implantation~~ (Deleted 01/01/2026)
	64567	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation

Codes	Number	Description
	64999	Unlisted procedure, nervous system
HCPCS	A4596	Cranial electrotherapy stimulation (ces) system supplies and accessories, per month
	E0732	Cranial electrotherapy stimulation (ces) system, any type
	E1399	Durable medical equipment, miscellaneous

Date of Origin: *April 2007*