

Medical Policy Manual

Topic: Cranial Electrostimulation Therapy (CES)

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Section: Durable Medical Equipment

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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. 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 treatment of stress, alcoholism and drug addiction, headache, cognitive dysfunction in head injured patients, psychiatric conditions, 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 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 SB1202-B and SB1201-M (Medical Consultants Intl., 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.

Notes:

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, DME-83 for an index of other electrical stimulation policies).

Other uses of microcurrent stimulation are addressed in Medical Policy, DME, Policy No. 83.03, [Microcurrent Stimulation \(MENS\)](#).

MEDICAL POLICY CRITERIA

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

1. Alzheimer's disease
2. Anxiety
3. Apathy related to traumatic brain injury
4. Chemical dependence / substance abuse
5. Chronic pain related to spinal cord injury
6. Cognitive dysfunction
7. Depressive symptoms
8. Fibromyalgia

9. Headache
10. Smoking cessation
11. Sleep disturbances
12. Stress related conditions
13. Tinnitus
14. Traumatic brain injury

SCIENTIFIC EVIDENCE

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.

Literature Appraisal

Two Cochrane reviews, one focused on interventions for apathy in traumatic brain injury (TBI) and another comparing non-invasive treatments for chronic pain, were published. Additionally, several randomized controlled studies were published on the use of CES for a variety of indications.

Systematic Reviews/Technology Assessments

- A Cochrane review for treatment of apathy in traumatic brain injury found only one randomized controlled trial which met inclusion criteria for the review.^[2] However, the reviewers cautioned against making conclusions from this randomized controlled trial due to the small study size (n=21).
- Another Cochrane review and meta-analysis evaluated the use of CES as a non-invasive treatment for chronic pain.^[3] No differences were found in health outcomes when CES was compared with sham in the 3 studies which 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.

Randomized Controlled Trials (RCT)

A number of randomized controlled studies explored the efficacy of CES for a variety of conditions, including Alzheimer's disease, smoking cessation, chronic pain related to spinal cord injury, anxiety in patients receiving dental care, chemical dependence, sleep disturbances, depressive symptoms, fibromyalgia, and tinnitus.^[4-15] Overall, data from these studies were unreliable due to the following limitations:

- Small study populations, less than 100 patients total,^[4-12,16-18] limited the ability to rule out the role of chance as an explanation of study findings.
- Follow-up of study subjects was over a short period of time, less than 6 months, so the medium and long-term effects of CES treatment remain unknown.^[4-12,14,16,17,19,20]
- Use of co-therapies such as fibromyalgia medications^[10] and antidepressants^[6] were allowed but not adequately addressed in the analysis, potentially confounding the findings. In some instances the status of the patients regarding concurrent treatments was not addressed at all.^[8,16,17,19]
- Randomization methods were not clearly stated^[4,8,12] or weak methods of randomization were used.^[6,10,11,16,19] The latter did not provide sufficient evidence to support claims of adequate randomization, such as comparison of the active treatment and sham groups at study baseline.
- Some of the study designs allowed for treatment crossover after a specified wash-out period.^[6,12] As medium- and long-term effects of CES have not been evaluated or established, the appropriate wash-out period is difficult to define. In addition, crossover study populations were not necessarily subject to the same treatment parameters as active groups, undermining valid comparisons.^[12]
- 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^[8], rendered the study findings unreliable.
- Overall, the trials did not adequately explain the clinical significance of the changes observed in their outcomes of interest.^[21]
- 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.^[4,5]

Clinical Practice Guidelines

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

Based on the lack of published long-term objective outcomes from well-designed, well-executed randomized controlled clinical trials, conclusions cannot be reached concerning the effectiveness of cranial electrostimulation therapy as a treatment of pain or any other condition; therefore, cranial electrostimulation therapy (CES) is considered investigational for all indications. Larger, randomized, placebo- controlled trials of longer duration are needed to evaluate the effectiveness of CES devices in improving pain or mental health conditions and to determine whether CES offers any additional benefit compared with sham treatment or other standard treatments.

REFERENCES

1. Mueller, S, Chang, S. Pediatric brain tumors: current treatment strategies and future therapeutic approaches. *Neurotherapeutics*. 2009 Jul;6(3):570-86. PMID: 19560746
2. Lane-Brown, A, Tate, R. Interventions for apathy after traumatic brain injury. *Cochrane Database Syst Rev*. 2009(2):CD006341. PMID: 19370632
3. O'Connell, NE, Wand, BM, Marston, L, Spencer, S, Desouza, LH. Non-invasive brain stimulation techniques for chronic pain. A report of a Cochrane systematic review and meta-analysis. *Eur J Phys Rehabil Med*. 2011 Jun;47(2):309-26. PMID: 21494222
4. Scherder, E, Knol, D, van Someren, E, et al. Effects of low-frequency cranial electrostimulation on the rest-activity rhythm and salivary cortisol in Alzheimer's disease. *Neurorehabil Neural Repair*. 2003 Jun;17(2):101-8. PMID: 12814055
5. Scherder, EJ, van Tol, MJ, Swaab, DF. High-frequency cranial electrostimulation (CES) in patients with probable Alzheimer's disease. *Am J Phys Med Rehabil*. 2006 Jul;85(7):614-8. PMID: 16788393
6. Capel, ID, Dorrell, HM, Spencer, EP, Davis, MW. The amelioration of the suffering associated with spinal cord injury with subperception transcranial electrical stimulation. *Spinal Cord*. 2003 Feb;41(2):109-17. PMID: 12595874
7. Winick, RL. Cranial electrotherapy stimulation (CES): a safe and effective low cost means of anxiety control in a dental practice. *Gen Dent*. 1999 Jan-Feb;47(1):50-5. PMID: 10321152
8. Schmitt, R, Capo, T, Boyd, E. Cranial electrotherapy stimulation as a treatment for anxiety in chemically dependent persons. *Alcohol Clin Exp Res*. 1986 Mar-Apr;10(2):158-60. PMID: 3521373
9. Rose, KM, Taylor, AG, Bourguignon, C. Effects of cranial electrical stimulation on sleep disturbances, depressive symptoms, and caregiving appraisal in spousal caregivers of persons with Alzheimer's disease. *Appl Nurs Res*. 2009 May;22(2):119-25. PMID: 19427574
10. Lichtbroun, AS, Mei-Ming, C. The treatment of fibromyalgia with cranial electrotherapy stimulation. *J Clin Psychiatry*. 1984;45(2):60-3. PMID: No PMID Entry
11. Kapkin, O, Satar, B, Yetiser, S. Transcutaneous electrical stimulation of subjective tinnitus. A placebo-controlled, randomized and comparative analysis. *ORL J Otorhinolaryngol Relat Spec*. 2008;70(3):156-61. PMID: 18401195
12. Tan, G, Rintala, DH, Thornby, JI, Yang, J, Wade, W, Vasilev, C. Using cranial electrotherapy stimulation to treat pain associated with spinal cord injury. *J Rehabil Res Dev*. 2006 Jul-Aug;43(4):461-74. PMID: 17123186
13. Lichtbroun, AS, Raicer, MM, Smith, RB. The treatment of fibromyalgia with cranial electrotherapy stimulation. *J Clin Rheumatol*. 2001 Apr;7(2):72-8; discussion 8. PMID: 17039098
14. Pickworth, WB, Fant, RV, Butschky, MF, Goffman, AL, Henningfield, JE. Evaluation of cranial electrostimulation therapy on short-term smoking cessation. *Biol Psychiatry*. 1997 Jul 15;42(2):116-21. PMID: 9209728
15. Tan, G, Rintala, DH, Jensen, MP, et al. Efficacy of cranial electrotherapy stimulation for neuropathic pain following spinal cord injury: a multi-site randomized controlled trial with a secondary 6-month open-label phase. *J Spinal Cord Med*. 2011;34(3):285-96. PMID: 21756567
16. Sureda, A, Robinson, S, Canals, C, et al. Reduced-intensity conditioning compared with conventional allogeneic stem-cell transplantation in relapsed or refractory Hodgkin's lymphoma: an analysis from the Lymphoma Working Party of the European Group for Blood and Marrow Transplantation. *J Clin Oncol*. 2008 Jan 20;26(3):455-62. PMID: 18086796

17. Ochi, M, Saeki, S, Oda, T, Matsushima, Y, Hachisuka, K. Effects of anodal and cathodal transcranial direct current stimulation combined with robotic therapy on severely affected arms in chronic stroke patients. *J Rehabil Med*. 2013 Feb;45(2):137-40. PMID: 23306448
18. Taylor, AG, Anderson, JG, Riedel, SL, Lewis, JE, Bourguignon, C. A randomized, controlled, double-blind pilot study of the effects of cranial electrical stimulation on activity in brain pain processing regions in individuals with fibromyalgia. *Explore (NY)*. 2013 Jan-Feb;9(1):32-40. PMID: 23294818
19. Munshi, NC, Barlogie, B. Role for high-dose therapy with autologous hematopoietic stem cell support in Waldenstrom's macroglobulinemia. *Semin Oncol*. 2003 Apr;30(2):282-5. PMID: 12720153
20. Lande, RG, Gragnani, C. Efficacy of cranial electric stimulation for the treatment of insomnia: a randomized pilot study. *Complementary therapies in medicine*. 2013 Feb;21(1):8-13. PMID: 23374200
21. Brignani, D, Ruzzoli, M, Mauri, P, Miniussi, C. Is transcranial alternating current stimulation effective in modulating brain oscillations? United States, 2013. p. e56589.

CROSS REFERENCES

[Electrical Stimulation Devices Index](#), Durable Medical Equipment, Policy No. 83

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous