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Medical Policy Manual Durable Medical Equipment, Policy No. 83.06

Cranial Electrostimulation Therapy (CES)

Effective: February 1, 2019

Next Review: November 2019
Last Review: January 2019

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. Smoking cessation
K. Sleep disturbances
L. Stress related conditions
M. Tinnitus
N. 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. Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

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 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, 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)

- 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.

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

A 2018 systematic review (SR) prepared by Shekelle for the Department of Veterans Affairs Evidence-based Synthesis Program (ESP) synthesized evidence on CES for chronic pain, depression, anxiety, insomnia, and posttraumatic stress disorder (PTSD).[2] 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.[3-5] 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.[6] 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.

A 2014 Cochrane SR by Kavirajan assessed the efficacy and safety of CES as a treatment of acute depression compared to sham or simulated CES treatment.[7] 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.[8] However, the reviewers cautioned against making conclusions from this RCT due to the small study size (n=21).

RANDOMIZED CONTROLLED TRIALS

Roh and Wi-Young (2017) published an RCT that evaluated how CES aids in improving symptoms of depression and anxiety, by evaluating behaviors and certain hormones[9] 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, and tinnitus.[10-20] In addition, several RCTs not included in the reviews above were also identified.[21,22] Overall, data from these studies were unreliable due to a variety of limitations, including small study populations,[10-16,19,23,24] short follow-up of study subjects,[10-16,18,23-25] confounding use of co-therapies such as fibromyalgia medications[15] and antidepressants[21] , weak or unclear randomization methods,[10,13,15,16] 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[13], rendered the study findings unreliable.

Overall, the RCTs did not adequately explain the clinical significance of the changes observed in their outcomes of interest.[26] 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.[10,11]

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.

REFERENCES

1. Gunther, M, Phillips, KD. Cranial electrotherapy stimulation for the treatment of depression. *Journal of psychosocial nursing and mental health services*. 2010 Nov;48(11):37-42. PMID: 20669869
2. Shekelle, P, Cook, I, Miake-Lye, IM, et al. The Effectiveness and Risks of Cranial Electrical Stimulation for the Treatment of Pain, Depression, Anxiety, PTSD, and Insomnia: A Systematic Review. Washington DC; 2018.
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. O'Connell, NE, Wand, BM, Marston, L, Spencer, S, Desouza, LH. Non-invasive brain stimulation techniques for chronic pain. *Cochrane Database Syst Rev*. 2014;4:CD008208. PMID: 24729198
5. O'Connell, NE, Marston, L, Spencer, S, DeSouza, LH, Wand, BM. Non-invasive brain stimulation techniques for chronic pain. *Cochrane Database Syst Rev*. 2018 Apr 13;4:CD008208. PMID: 29652088
6. Boldt, I, Eriks-Hoogland, I, Brinkhof, MW, de Bie, R, Joggi, D, von Elm, E. Non-pharmacological interventions for chronic pain in people with spinal cord injury. *Cochrane Database Syst Rev*. 2014;11:CD009177. PMID: 25432061
7. Kavirajan, HC, Lueck, K, Chuang, K. Alternating current cranial electrotherapy stimulation (CES) for depression. *Cochrane Database Syst Rev*. 2014;7:CD010521. PMID: 25000907
8. Lane-Brown, A, Tate, R. Interventions for apathy after traumatic brain injury. *Cochrane Database Syst Rev*. 2009(2):CD006341. PMID: 19370632
9. Roh, HT, So, WY. Cranial electrotherapy stimulation affects mood state but not levels of peripheral neurotrophic factors or hypothalamic- pituitary-adrenal axis regulation. *Technology and health care : official journal of the European Society for Engineering and Medicine*. 2017;25(3):403-12. PMID: 27886020
10. 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
11. 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

12. 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
13. 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
14. 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
15. 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
16. 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
17. 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
18. 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
19. Lee, SH, Kim, WY, Lee, CH, et al. Effects of cranial electrotherapy stimulation on preoperative anxiety, pain and endocrine response. *J Int Med Res*. 2013;41:1788-95. PMID: 24265330
20. Gong, BY, Ma, HM, Zang, XY, et al. Efficacy of Cranial Electrotherapy Stimulation Combined with Biofeedback Therapy in Patients with Functional Constipation. *Journal of neurogastroenterology and motility*. 2016 Jul 30;22(3):497-508. PMID: 26932836
21. Barclay, TH, Barclay, RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of affective disorders*. 2014 Aug;164:171-7. PMID: 24856571
22. McClure, D, Greenman, SC, Koppolu, SS, Varvara, M, Yaseen, ZS, Galynker, II. A Pilot Study of Safety and Efficacy of Cranial Electrotherapy Stimulation in Treatment of Bipolar II Depression. *The Journal of nervous and mental disease*. 2015 Nov;203(11):827-35. PMID: 26414234
23. 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. *Journal of rehabilitation medicine : official journal of the UEMS European Board of Physical and Rehabilitation Medicine*. 2013 Feb;45(2):137-40. PMID: 23306448
24. Tyler, ME, Kaczmarek, KA, Rust, KL, Subbotin, AM, Skinner, KL, Danilov, YP. Non-invasive neuromodulation to improve gait in chronic multiple sclerosis: a randomized double blind controlled pilot trial. *J Neuroeng Rehabil*. 2014;11:79. PMID: 24885412
25. 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
26. Brignani, D, Ruzzoli, M, Mauri, P, Miniussi, C. Is transcranial alternating current stimulation effective in modulating brain oscillations? *PLoS One*. 2013;8:e56589. PMID: 23457586

CODES

Codes	Number	Description
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous

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