Medical Coverage Policy | Cranial Electrotherapy Stimulation and Auricular Electrostimulation

EFFECTIVE DATE: 03|07|2017
POLICY LAST UPDATED: 02|17|2021

OVERVIEW
Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices. Auricular electrostimulation involves stimulation of acupuncture points on the ear. CES is being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and functional constipation. Auricular electrical stimulation is being evaluated for pain, weight loss, and opioid withdrawal.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Electrical stimulation of auricular acupuncture points is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Electrical stimulation of auricular acupuncture points is not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Cranial electrotherapy stimulation, (CES) also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, weight loss and opioid withdrawal.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

Regulatory Status

A number of devices for cranial electrotherapy stimulation have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing through the 510(k) process.

Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain who receive CES, the evidence includes a number of small sham-controlled randomized trials and pooled analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Three trials studied headache and CES, and 65 trials studied chronic pain and CES. Pooled analyses found marginal benefits for a headache with CES and no benefits for chronic pain with CES. A subsequent sham-controlled trial of remotely supervised CES via secure videoconferencing found a significant benefit with CES for pain reduction, but it had important relevance and conduct and design limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric, behavioral, or neurologic conditions (eg, depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and a systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. Only 1 RCT found a significant benefit with CES for depression, but it had important relevance limitations. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease, and smoking cessation and tic disorders do not support the use of CES for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have functional constipation who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The single RCT reported positive results for the treatment of constipation with CES. However, the trial was unblinded, and most outcomes were self-reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Auricular Electrostimulation

For individuals who have acute or chronic pain (eg, acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis or rheumatoid arthritis) who receive auricular electrostimulation, the

evidence includes a limited number of trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Studies evaluating the effect of electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham-control group, and, in a study of rheumatoid arthritis, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in visual analog scale pain scores of unclear clinical significance. Overall, the few published studies have small sample sizes and methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs. and one systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes 2 case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Both case series report positive outcomes for the use of CES to treat opioid withdrawal symptoms. The studies used different treatment protocols and no comparators, limiting conclusions drawn from the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Therefore, these services are not covered for Medicare Advantage Plans and not medically necessary for Commercial products.

CODING

Medicare Advantage Plans and Commercial Products

There is no specific CPT or HCPCS code for Cranial electrotherapy stimulation; therefore providers should report this service with an unlisted procedure code.

The following HCPCS codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial products:

K1002 Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type

S8930 Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

RELATED POLICIES

None

PUBLISHED

Provider Update, April 2021
Provider Update, May 2020
Provider Update, June 2019
Provider Update, May 2018
Provider Update, May 2017

REFERENCES

1. Klawansky S, Yeung A, Berkey C, et al. Meta-analysis of randomized controlled trials of cranial electrostimulation. Efficacy in treating selected psychological and physiological conditions. J Nerv Ment Dis. Jul 1995;183(7):478-484. PMID 7623022
2. Bronfort G, Nilsson N, Haas M, et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. Jul 2004(3):CD001878. PMID 15266458
3. O'Connell NE, Wand BM, Marston L, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Apr 11 2014;4(4):CD008208. PMID 24729198

4. Kavirajan HC, Lueck K, Chuang K. Alternating current cranial electrotherapy stimulation (CES) for depression. Cochrane Database Syst Rev. Jul 8 2014;7:CD010521. PMID 25000907
5. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. Aug 2014;164:171-177. PMID 24856571
6. Mischoulon D, De Jong MF, Vitolo OV, et al. Efficacy and safety of a form of cranial electrical stimulation (CES) as an add-on intervention for treatment-resistant major depressive disorder: A three week double blind pilot study. J Psychiatr Res. Nov 2015;70:98-105. PMID 26424428
7. Lyon D, Kelly D, Walter J, et al. Randomized sham controlled trial of cranial microcurrent stimulation for symptoms of depression, anxiety, pain, fatigue and sleep disturbances in women receiving chemotherapy for early-stage breast cancer. Springerplus. Oct 2015;4:369. PMID 26435889
8. Shill HA, Obradov S, Katsnelson Y, et al. A randomized, double-blind trial of transcranial electrostimulation in early Parkinson's disease. Mov Disord. Jul 2011;26(8):1477-1480. PMID 21538515
9. Pickworth WB, Fant RV, Butschky MF, et al. Evaluation of cranial electrostimulation therapy on short-term smoking cessation. Biol Psychiatry. Jul 15 1997;42(2):116-121. PMID 9209728
10. Gong BY, Ma HM, Zang XY, et al. Efficacy of cranial electrotherapy stimulation combined with biofeedback therapy in patients with functional constipation. J Neurogastroenterol Motil. Jul 30 2016;22(3):497-508. PMID 26932836
11. Sator-Katzenschlager SM, Michalek-Sauberer A. P-Stim auricular electroacupuncture stimulation device for pain relief. Expert Rev Med Devices. Jan 2007;4(1):23-32. PMID 17187468
12. Holzer A, Leitgeb U, Spacek A, et al. Auricular acupuncture for postoperative pain after gynecological surgery: a randomized controlled trail. Minerva Anestesiol. Mar 2011;77(3):298-304. PMID 21441884
13. Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, et al. The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture. Anesth Analg. May 2004;98(5):1359-1364, table of contents. PMID 15105215
14. Sator-Katzenschlager SM, Szeles JC, Scharbert G, et al. Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study. Anesth Analg. Nov 2003;97(5):1469-1473. PMID 14570667
15. Bernateck M, Becker M, Schwake C, et al. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: a randomized controlled trial. Auricular acupuncture and autogenic training in rheumatoid arthritis. Forsch Komplementmed. Aug 2008;15(4):187-193. PMID 18787327
16. Kim SY, Shin IS, Park YJ. Effect of acupuncture and intervention types on weight loss: a systematic review and meta-analysis. Obes Rev. Nov 2018;19(11):1585-1596. PMID 30180304
17. Schukro RP, Heiserer C, Michalek-Sauberer A, et al. The effects of auricular electroacupuncture on obesity in female patients--a prospective randomized placebo-controlled pilot study. Complement Ther Med. Feb 2014;22(1):21-25. PMID 24559812
18. Yeh ML, Chu NF, Hsu MY, et al. Acupoint stimulation on weight reduction for obesity: a randomized shamcontrolled study. West J Nurs Res. Dec 2015;37(12):1517-1530. PMID 25183702
19. Kroening RJ, Oleson TD. Rapid narcotic detoxification in chronic pain patients treated with auricular electroacupuncture and naloxone. Int J Addict. Sep 1985;20(9):1347-1360. PMID 2867052
20. Miranda A, Taca A. Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: a multisite, retrospective assessment. Am J Drug Alcohol Abuse. 2018;44(1):56-63. PMID 28301217
21. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. Aug 2014;164:171-177. PMID 24856571
23.Mischoulon D, De Jong MF, Vitolo OV, et al. Efficacy and safety of a form of cranial electrical stimulation (CES) as an add-on intervention for treatment-resistant major depressive disorder: A three week double blind pilot study. J Psychiatr Res. Nov 2015;70:98-105. PMID 26424428
24. Ahn H, Galle K, Mathis KB, et al. Feasibility and efficacy of remotely supervised cranial electrical stimulation for pain in older adults with knee osteoarthritis: A randomized controlled pilot study. J Clin Neurosci. Jul 2020; 77: 128-133. PMID 32402609

25.. Shekelle PG, Cook IA, Miake-Lye 22.IM et al. Benefits and Harms of Cranial Electrical Stimulation for Chronic Painful Conditions, Depression, Anxiety, and Insomnia: A Systematic Review.. Ann. Intern. Med., 2018 Feb 13;168(6). PMID 29435567 .

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.