Medical Coverage Policy | Cranial Electrotherapy Stimulation and Auricular Electrostimulation

EFFECTIVE DATE: 06|01|2023
POLICY LAST REVIEWED: 05|06|2026

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 such as the Alpha-Stim. Auricular electrostimulation involves the 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 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 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 that the technology results in an improvement in the net health outcome.

Commercial Products
Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is not medically necessary as 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 medically necessary as the evidence is insufficient to determine. that the technology results in an improvement in the net health outcome.

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 the 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 CES 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 Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Indications
Genesis Sleep	Neurofield, Inc.	Insomnia
Proliv™Rx System	Neurolief, Ltd.	Depression
Flow FL-100	Flow Neuroscience AB	Depression
Modius Lean	Neurovalens Limited	Weight management
Modius Stress	Neurovalens Limited	Generalized anxiety disorder
Modius Sleep	Neurovalens Limited	Insomnia
Cervella™	Innovative Neurological Devices	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	Insomnia, depression, anxiety

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by the FDA through the 510(k) process:

Auricular Electrostimulation Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Indication

NET Device™	Net Recovery	Reduce symptoms of opioid withdrawal
Sparrow Ascent®	Spark Biomedical, Inc.	Reduce symptoms of opioid withdrawal
Needle Stimulator	Wuxi Jiajian Medical Instrument	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, INC.	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1®	DyAnsys Inc	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	Reduce symptoms of opioid withdrawal
Drug Relief	DyAnsys Inc	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	Substance use disorders
Stivax System	Biegler Gmbh	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®	DyAnsys Inc	Practice of acupuncture by qualified practitioners as determined by the states
Pantheon Electrostimulator	Pantheon Research	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	Practice of acupuncture by qualified practitioners as determined by the states
JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	Unknown - Summary not provided
Electro-Acupuncture: Aculife/ModelADOC-01	Inno-Health Technology, Inc.	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse	Medevice Corporation	Practice of acupuncture by qualified practitioners as determined by the states
Model ES-130	Ito Co., Ltd.	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Neuroscience Therapy Corp.	Practice of acupuncture by qualified practitioners as determined by the states

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. Systematic reviews of randomized trials evaluated CES for headache and chronic pain. 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. Seven randomized controlled trials (RCTs) evaluated CES for depression and anxiety. One RCT found a significant benefit with CES for anxiety or depression and 3 RCTs found a significant benefit for depression, but all 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, 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 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.

For individuals who have obesity who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCT did not find a difference in weight loss between CES and a sham device. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have insomnia who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The trial found that CES significantly decreased Insomnia Severity Scores at 4 weeks compared to a sham device, but the number of patients that experienced a clinically meaningful change in insomnia scores was not fully described. 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 systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The systematic reviews are limited by high heterogeneity with respect to the interventions used, participants included, treatment period, and outcome measures. 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 an RCT and 2 observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCT found that opioid withdrawal symptoms were lower with active stimulation than sham stimulation, but the study was small and had limited follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products

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

0783T Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
A4543 Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4596 Cranial electrotherapy stimulation (ces) system supplies and accessories, per month
E0721 Transcutaneous electrical nerve stimulator for nerves in the auricular region
E0732 Cranial electrotherapy stimulation (ces) system, 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, July 2026
Provider Update, May 2025
Provider Update, May 2024
Provider Update, April 2023
Provider Update, June 2022

REFERENCES

1. U.S. Food & Drug Administration. FDA News Release: FDA grants marketing authorization of the first device for use in helping to reduce the symptoms of opioid withdrawal. https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal. November 15, 2017. Accessed December 22, 2025.
2. 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): 478-84. PMID 7623022
3. Bronfort G, Nilsson N, Haas M, et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. 2004; (3): CD001878. PMID 15266458
4. Brønfort G, Haas M, Evans RL, et al. WITHDRAWN: Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. Aug 26 2014; 2014(8): CD001878. PMID 25157618
5. 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): CD008208. PMID 24729198
6. O'Connell NE, Marston L, Spencer S, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Mar 16 2018; 3(3): CD008208. PMID 29547226
7. 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. PMID32402609
8. Price L, Briley J, Haltiwanger S, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. J Psychiatr Res. Mar 2021; 135: 119-134. PMID 33477056
9. Ching PY, Hsu TW, Chen GW, et al. Efficacy and Tolerability of Cranial Electrotherapy Stimulation in the Treatment ofAnxiety: A Systemic Review and Meta-Analysis. Front Psychiatry. 2022; 13: 899040. PMID 35757229
10. Liu SY, Chen R, Wang CH, et al. Efficacy of cranial electrotherapy stimulation for treating primary and secondary depression in adults: A meta-analysis of randomized controlled trials. J Affect Disord. Aug 01 2025; 382: 488-497. PMID40286924
11. Patel S, Boutry C, Patel P, et al. A randomised controlled trial investigating the clinical and cost-effectiveness of Alpha-Stim AID cranial electrotherapy stimulation (CES) in patients seeking treatment for moderate severity depression in primary care (Alpha-Stim-D Trial). Trials. Apr 04 2022; 23(1): 250. PMID 35379314

12. Morriss R, Patel S, Boutry C, et al. Clinical effectiveness of active Alpha-Stim AID versus sham Alpha-Stim AID in major depression in primary care in England (Alpha-Stim-D): a multicentre, parallel group, double-blind, randomised controlled trial. Lancet Psychiatry. Mar 2023; 10(3): 172-183. PMID 36724796
13. Kim J, Kim H, Kim DH, et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord. Dec 01 2021; 295: 856-864.PMID 34706456
14. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. Aug 2014; 164: 171-7. PMID 24856571
15. Shekelle PG, Cook IA, Miake-Lye IM, et al. Benefits and Harms of Cranial Electrical Stimulation for Chronic Painful Conditions, Depression, Anxiety, and Insomnia: A Systematic Review. Ann Intern Med. Mar 20 2018; 168(6): 414-421.PMID 29435567
16. 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
17. 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. 2015; 4: 369. PMID 26435889
18. Gehrman PR, Bartky EJ, Travers C, et al. A Fully Remote Randomized Trial of Transcranial Alternating Current Stimulation for the Acute Treatment of Major Depressive Disorder. J Clin Psychiatry. Apr 22 2024; 85(2). PMID 38696220
19. Woodham RD, Selvaraj S, Lajmi N, et al. Home-based transcranial direct current stimulation treatment for major depressive disorder: a fully remote phase 2 randomized sham-controlled trial. Nat Med. Jan 2025; 31(1): 87-95. PMID39433921
20. Carpenter LL, George MS, Navarro N, et al. A novel home-based, combined occipital and trigeminal afferent stimulation therapy for major depressive disorder: Efficacy and safety results from a double-blind multicenter randomized sham-controlled study. Brain Stimul. 2025; 18(5): 1695-1704. PMID 40886913
21. 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): 1477-80. PMID 21538515
22. 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): 116-21. PMID 9209728
23. Wu WJ, Wang Y, Cai M, et al. A double-blind, randomized, sham-controlled study of cranial electrotherapy stimulation as an add-on treatment for tic disorders in children and adolescents. Asian J Psychiatr. Jun 2020; 51: 101992. PMID32145674
24. 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
25. Viirre E, Sittlington J, Wing D, et al. Non-invasive vestibular nerve stimulation (VeNS) reduces visceral adipose tissue: results of a randomised controlled trial. Sci Rep. Mar 13 2025; 15(1): 8753. PMID 40082596
26. Curry G, Cheung T, Zhang SD, et al. Repeated electrical vestibular nerve stimulation (VeNS) reduces severity in moderate to severe insomnia; a randomised, sham-controlled trial; the modius sleep study. Brain Stimul. 2024; 17(4): 782-793.PMID 38797370
27. U.S. Food and Drug Administration. Genesis Sleep Device Approval Summary. December 2025.https://www.accessdata.fda.gov/cdrh_docs/pdf25/K252951.pdf. Accessed March 13, 2026
28. 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
29. 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
30. Ilfeld BM, Abramson WB, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following cholecystectomy and hernia repair: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Sep 02 2024; 49(9): 628-634. PMID 38388014

31. Ilfeld BM, Finneran JJ, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following total knee arthroplasty: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Jan 07 2025; 50(1): 26-35. PMID 38388019
32. Ilfeld BM, Said ET, Alexander BS, et al. Pain Management Following Total Hip Arthroplasty With Percutaneous AuricularStimulation (Neuromodulation): A Randomized, Double-Masked, Sham-Controlled Pilot Study. Cureus. Feb 2025; 17(2):e78920. PMID 40091968
33. Ilfeld BM, Abramson WB, Said ET, et al. Percutaneous auricular neuromodulation to treat pain after ambulatory breast surgery: A randomized, double-masked, sham-controlled pilot study. Can J Pain. 2025; 9(1): 2521117. PMID 40657450
34. 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): 1359-64,table of contents. PMID 15105215
35. 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
36. 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): 187-93. PMID 18787327
37. 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
38. Yeh TL, Chen HH, Pai TP, et. al. The Effect of Auricular Acupoint Stimulation in Overweight and Obese Adults: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Evidence-Based Complementary and Alternative Medicine. 2017; vol. 2017, Article ID 3080547, 16 pages, 2017. https://doi.org/10.1155/2017/3080547.
39. 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): 21-5. PMID24559812
40. Yeh ML, Chu NF, Hsu MY, et al. Acupoint Stimulation on Weight Reduction for Obesity: A Randomized Sham-Controlled Study. West J Nurs Res. Dec 2015; 37(12): 1517-30. PMID 25183702
41. Greenwald MK, Arfken CL, Winston JR. A randomized, sham-controlled clinical trial to evaluate the NET Device™ for reducing withdrawal symptom severity during opioid discontinuation. Front Psychiatry. 2025; 16: 1510428. PMID40046990
42. Kroening RJ, Oleson TD. Rapid narcotic detoxification in chronic pain patients treated with auricular electroacupuncture and naloxone. Int J Addict. Sep 1985; 20(9): 1347-60. PMID 2867052
43. 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