

MEDICAL POLICY – 8.01.540

Cranial Electrotherapy Stimulation and Auricular Electrostimulation

BCBSA Ref. Policy: 8.01.58

Effective Date: May 1, 2024

Last Revised: Oct. 1, 2024

Replaces: 8.01.58

RELATED MEDICAL POLICIES:


1.01.507 Electrical Stimulation Devices

2.01.526 Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

Introduction

Cranial electrotherapy stimulation (CES) provides weak levels of electrical current to the brain. Electrodes are placed on the skull, earlobes, eyelids, or forehead. A small transmitter then sends weak electrical pulses into the brain. It's believed the current affects particular areas of the brain that play important roles in the body's hormones and emotions. Another use of CES calls for treating pain by placing the electrodes near the site of pain. Auricular stimulation sends electrical pulses to the acupuncture points of the ear. Both of these systems have been used for depression, anxiety, insomnia (sleeplessness), and weight loss. Because there is not enough medical evidence showing that these technologies improve health, both are considered unproven. A small device worn behind the ear that stimulates specific nerves to try to relieve symptoms of opioid withdrawal is unproven. More research is needed to determine if this device is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can

be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Procedure	Investigational
Cranial electrotherapy stimulation	Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is investigational in all situations.
Auricular electrostimulation	<p>Electrical stimulation of auricular acupuncture points is investigational in all situations.</p> <p>Electrical stimulation of the ear (also known as auricular neurostimulation) for opioid withdrawal is investigational.</p>

Coding

Code	Description
CPT	
0783T	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
HCPCS	
A4543	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month (New code effective 10/1/2024)
A4596	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
E0721	Transcutaneous electrical nerve stimulator for nerves in the auricular region (New code effective 10/1/2024)
E0732	Cranial electrotherapy stimulation (CES) system, any type (new code effective 1/1/2024)
K1002	Cranial electrotherapy stimulation (CES) system, any type (code termed 1/1/2024)
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient



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Related Information

N/A

Evidence Review

Description

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 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.

Background

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



USS.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression. The 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 three 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.

Summary of Evidence

Cranial Electrotherapy Stimulation

For individuals with acute or chronic pain who receive CES the evidence includes a number of small sham-controlled randomized trials and pooled analyses. The 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 with psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and systematic reviews. The relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. One RCT each found a significant benefit with CES for anxiety or depression, but both 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 an RCT. The 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 with acute or chronic pain (e.g., 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. The 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. The 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 two observational studies. The relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Both studies 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.

Ongoing and Unpublished Clinical Trials

Table 1 provides a summary of ongoing and unpublished trials that may influence this review.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03825471	Effects of Cranial Electrotherapy Stimulation on Anesthetics Consumption, Perioperative Cytokines Response, and Postoperative Pain in Patients Undergoing Colonic Surgery	80	Dec 2020
NCT03896438	Increased Thalamocortical Connectivity in Tdcs-potentiated Generalization of Cognitive Training	85	April 2024
Unpublished			
NCT05384041	Cranial Electrotherapy Stimulation for the Treatment of Major Depressive Disorder in Adults	255	Oct 2022
NCT03815253	Electro-acupuncture for Central Obesity	168	Feb 2021
NCT03060122	The Clinical Feasibility of Combining Cranial Electrotherapy Stimulation (CES Alpha-Stim) and Non-invasive Interactive Neurostimulation (InterX) for Optimized Rehabilitation Following Extremity Immobilization	35	Aug 2019

NCT: national clinical trial

^a Denotes industry sponsorship

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.



While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2011 Input

In response to requests, input on auricular electrostimulation was received from three physician specialty societies and five academic medical centers while this policy was under review in 2011. There was a consensus that auricular electrostimulation is investigational.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

A number of devices for CES have been cleared for marketing by the US Food and Drug Administration's (FDA) 510(k) process. In 1992, the Alpha-Stim CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Devices cleared since 2000 are summarized in [Table 2](#).

FDA product code: QJQ.



Table 2: Cranial Electrotherapy Stimulation (CES) Devices Cleared by the US Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
Modius Sleep	Neurovalens Limited	10/27/2023	K230826	Insomnia
Cervella	Innovative Neurological Devices	03/07/2019	K182311	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	05/29/2009	K090052	Insomnia, depression, anxiety
Elexoma Medic	Redplane AG	05/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra	Neuro-Fitness	04/05/2007	K062284	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/2006	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	07/21/2003	K024377	Insomnia, depression, anxiety

FDA: Food and Drug Administration

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by FDA through the 510(k) process. Devices cleared since 2000 are summarized in [Table 3](#).

FDA product code: BWK, PZR.

Table 3: Auricular Electrostimulation Devices Cleared by the US Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
Needle Stimulator	Wuxi Jijian Medical Instrument	08/27/2021	K202861	Practice of acupuncture by qualified practitioners of



Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
				acupuncture as determined by the states
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, INC.	02/03/2021	K200636	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1	DyAnsys Inc	11/05/2021	K211971	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	01/02/2021	K201873	Reduce symptoms of opioid withdrawal
Drug Relief	DyAnsys	05/02/2018	K173861	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	03/09/2017	K170391	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017	N/A ^a	Substance use disorders
Stivax System	Biegler GmbH	05/26/2016	K152571	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
ANSiStim	DyAnsys Inc	05/15/2015	K141168	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Pantheon Electrostimulator	Pantheon Research	11/07/2014	K133980	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	10/02/2014	K140530	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
P-Stim	Biegler GMBH	06/27/2014	K140788	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states



Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	08/16/2013	K130768	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Jiajian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	04/11/2013	K122812	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	08/05/2010	K093322	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc.	04/02/2010	K091933	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
e-Pulse	Medevice Corporation	12/07/2009	K091875	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Model ES-130	Ito Co., Ltd.	11/24/2008	K081943	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
P-Stim	NeuroScience Therapy Corp	03/30/2006	K050123	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Aculife	Inno-Health Technology, Inc.	03/28/2006	K051197	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AcuStim	S.H.P. Intl. Pty., Ltd.	06/12/2002	K014273	As an electroacupuncture device

^a "FDA cleared the NSS-2 Bridge Device for Substance Use Disorders through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence"¹

N/A: Not applicable



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History

Date	Comments
11/08/11	New policy; add to Therapy section. Policy created with literature search through April 2011; clinical input reviewed; considered investigational.



Date	Comments
11/13/12	Replace policy. Policy updated with literature review through June 2012, references 1-7 added; cranial electrotherapy stimulation (CES) added as investigational. "Cranial Electrotherapy Stimulation (CES)" added to policy title.
01/22/13	Update Related Policies. 2.01.50 has been replaced with 2.01.526.
02/15/13	Update Related Policies. Change title to policy 2.01.526.
10/14/13	Replace policy. Policy updated with literature review through July 10, 2013; policy statement unchanged.
11/20/14	Annual Review. Policy updated with literature review through July 16, 2014. References 4-5, 7, and 14 added; others renumbered. Policy statement unchanged.
10/13/15	Annual Review. Policy updated with literature review through July 6, 2015; no references added. Policy statements unchanged. Related policies updated; 2.01.526 removed.
05/01/16	Annual Review, approved April 12, 2016. Policy updated with literature review through December 10, 2015; references 6-7 added. Policy statement unchanged.
06/01/17	Annual Review, approved May 2, 2017. Policy updated with literature review through December 22, 2016; references 8 and 12 added. Policy statements unchanged.
10/17/17	Coding update; added CPT code 20974.
08/01/18	Annual Review, approved July 10, 2018. Policy updated with literature review through April 2018; 17-19 references added. Added electrical stimulation of the ear (also known as auricular neurostimulation) for opioid withdrawal is investigational. Removed CPT code 20974.
05/01/19	Annual Review, approved April 18, 2019. Policy updated with literature review through January 2019; reference 16 added. Policy statements unchanged.
01/01/20	Coding update, added HCPCS code K1002 (new code effective 1/1/20).
05/01/20	Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; references added. Policy statements unchanged. Removed CPT codes 97813 and 97814.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through December 14, 2020; references added. Policy statements unchanged.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through December 10, 2021; references added. Policy statements unchanged.
10/01/22	Coding update. Updated description of HCPCS code K1002.
11/01/22	Coding update. Added HCPCS code A4596.
01/01/23	Coding update. Added new CPT code 0783T. Added HCPC code L8692.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 27, 2022; references added. Policy statements unchanged.



Date	Comments
10/04/23	Updated related policy. Policy 7.01.29 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy was renumbered to 7.01.588 Percutaneous Electrical Nerve Stimulation and Percutaneous Neuromodulation Therapy.
01/01/24	Coding update. Added new HCPCS code E0732 and added term date to HCPCS code K1002.
05/01/24	Policy renumbered from 8.01.58 to 8.01.540 Cranial Electrotherapy Stimulation and Auricular Electrostimulation, approved April 9, 2024. Policy updated with literature review through January 3, 2024; reference added. Policy statements unchanged. Removed HCPCS L8692.
10/01/24	Coding update. Added new HCPCS codes A4543 and E0721 for the Sparrow Ascent effective 10/01/2024.

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