



# Louisiana

## **Cranial Electrotherapy Stimulation and Auricular Electrostimulation**

**Policy #** 00316

**Original Effective Date:** 10/19/2011

**Current Effective Date:** 11/01/2024

**Retired Date:** 12/15/2012

**Returned to Active Status:** 11/01/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders is addressed separately in medical policy 00121.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) in all situations to be **investigational**.\*

Based on review of the available data, the use of electrical stimulation of auricular acupuncture points in all situations is considered to be **investigational**.\*

### **Background/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. Cranial electrotherapy stimulation 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.

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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 3 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.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**

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. Devices cleared since 2000 are summarized in Table 1.

**Table 1. Cranial Electrotherapy Stimulation Devices Cleared by the U.S. Food and Drug Administration**

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
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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

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

FDA product codes: BWK, PZR

Devices cleared since 2000 are summarized in Table 2.

**Table 2. Auricular Electrostimulation Devices Cleared by the U.S. Food and Drug Administration**

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

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Drug Relief	DyAnsys Inc	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 <sup>a</sup>	Substance use disorders
Stivax System	Biegler Gmbh	05/26/2016	K152571	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim <sup>®‡</sup>	DyAnsys Inc	05/15/2015	K141168	Practice of acupuncture by qualified practitioners 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 as determined by the states

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P-Stim	Biegler GMBH	06/27/2014	K140788	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	08/16/2013	K130768	Practice of acupuncture by qualified practitioners 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 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 as determined by the states
e-Pulse	Medevice Corporation	12/07/2009	K091875	Practice of acupuncture by qualified practitioners as determined by the states

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Model ES-130	Ito Co., Ltd.	11/24/2008	K081943	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Neuroscience Therapy Corp.	03/30/2006	K050123	Practice of acupuncture by qualified practitioners as determined by the states
Aculife	Inno-Health Technology, Inc.	03/28/2006	K051197	Practice of acupuncture by qualified practitioners 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"

N/A: Not applicable

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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### 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 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. Cranial electrotherapy stimulation 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.

### Summary of Evidence

#### Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain who receive cranial electrotherapy stimulation (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 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 systematic reviews. 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.

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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 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 2 observational studies. 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

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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.

### **Supplemental Information**

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

#### **Clinical Input From Physician Specialty Societies and Academic Medical Centers**

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 3 physician specialty societies and 5 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 in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or 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.

#### **U.S. Preventive Services Task Force Recommendations**

Not applicable.

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### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Table 3 provides a summary of ongoing and unpublished trials that may influence this review.

**Table 3 Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03825471	Effects of Cranial Electrotherapy Stimulation on Anesthetics Consumption, Perioperative Cytokines Response, and Postoperative Pain in Patients Undergoing Colonic Surgery	80	December 2020 (status unknown)
NCT03896438	Increased Thalamocortical Connectivity in Tdcs-potentiated Generalization of Cognitive Training	85	April 2024
<i>Unpublished</i>			
NCT05384041	Cranial Electrotherapy Stimulation for the Treatment of Major Depressive Disorder in Adults	255	October 2022

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NCT03815253	Electro-acupuncture for Central Obesity	168	February 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	August 2019

NCT: national clinical trial.

<sup>a</sup> Denotes industry sponsorship.

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### **Policy History**

Original Effective Date: 10/19/2011

Current Effective Date: 11/01/2024

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|------------|--|
| 10/06/2011 | Medical Policy Committee review  |
| 10/19/2011 | Medical Policy Implementation Committee approval. New policy   |
| 02/02/2012 | Medical Policy Committee review  |
| 02/15/2012 | Medical Policy Implementation Committee approval. Retired policy.  |
| 10/03/2024 | Medical Policy Committee review  |
| 10/08/2024 | Medical Policy Implementation Committee approval. Brought back to active status. Title changed from "Auricular Electrostimulation" to "Cranial Electrotherapy Stimulation and Auricular Electrostimulation." Content added to match policy intent. |

Next Scheduled Review Date: 10/2025

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Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Policy # 00316  
 Original Effective Date: 10/19/2011  
 Current Effective Date: 11/01/2024  
 Retired Date: 12/15/2012  
 Returned to Active Status: 11/01/2024

**Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0783T, 63650, 64555
HCPCS	A4543, A4596, E0721, E0732, L8680, S8930
ICD-10 Diagnosis	All related diagnoses

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## Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Policy # 00316

Original Effective Date: 10/19/2011

Current Effective Date: 11/01/2024

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\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

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